EPA Registration No. 72977-3
Volume No. 1

TASK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II
For PRIA Submissions

A	Completed by Product Manager		
PRODUCT REVIEWER: KILLIAN SWIFT			RMB II TEAM 34
Description of Action: NOTIFICATION			EPA File Symbol/Reg No. 72977-3
Decision No. 365088	Submission No. 790743		Fee for Service Action Code:
FQPA Action Code: 332	Non-FQPA Action Code:		Fee for Service Fee: $

	MONTH	DAY	YEAR
APPLICATION DATE	02	10	2006
DATA PIN DATE	02	14	2006
REVIEWER ASSIGNED DATE			2006
DATE DUE FROM SCIENCE	----------	----------	2006
DATE DUE TO PM			2006
DATE DUE OUT OF AGENCY	03	10	

Type of Data:	PSB Product Chemistry ☐	PSB Acute Toxicology ☐	PSB Efficacy ☐	RASSB Environmental Fate ☐	RASSB Ecological Effects ☐	RASSB Chronic Toxicology ☐	RASSB Exposure ☐

COMMENTS:

ATTACHMENTS: ☒-LABELING ☒-CSF(S) ☒-DATA ☒-OTHERS

B	For Arctic Slope Contract Only	
Contractor: Arctic Slope	Contract No.: 0332	ARCTIC SLOPE/MANAGER
Draft Task: Signature _____ _____ (Est. hrs)	Final Task: Signature _____ _____ (Total hrs)	

C	Reviewer's Comments:

DATE FEE PAID:	RESPONSE CODE: 12 RESPONSE DATE: 7/1/06

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 1, 2006

Dolana Blount,
Regulatory Director
ETI H20
1725 Gillespie Way
El Cajon, CA 92020

Subject: **Axen 30**
EPA Registration No. 72977-3
Application Date: February 10, 2006
Receipt Date: February 14, 2006

Dear Ms. Blount:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c) 9.

Based on a review of the material submitted, the following comments apply:

The notification application is not acceptable for the following reasons:

1. Delete all label claims stating that this product provide residual activity against bacteria up to 24 hours after initial applications. Refer to Subdivision G, §91-2 (m).

2. The paragraph under the heading "General Information" must appear with sufficient prominence relative to other text and graphic (chart) material to assure that the instructions will not be overlooked under customary conditions of purchase and use.

3. On page 2 first paragraph, add asterisks or numbers to the word "bacteria and fungus" to correspond with the names of the bacteria and fungus listed in the chart.

Should you have any questions or comments concerning this letter, please contact me by telephone at 703-308-6422, email at heyward.adam@epa.gov or Killian Swift by telephone at 703-308-6346 or email at swift.killian@epa.gov.

Sincerely

Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

February 10, 2006

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attention: Adam Heyward

Subject: **Axen30, EPA Reg. No. : 72977-3**
Notification of other labeling revisions per PR Notice 98-10

Dear Mr. Heyward:

We are notifying of the following changes to the above referenced master label:

1. Clarification of option to include or delete the signal word "CAUTION" for this Category IV disinfectant. (Reference: Label Review Manual, 3rd Edition, Ch. 7, Section III.A.1 and III.A.2)

2. The following optional marketing phrases related to currently approved organism claims have been added:
   - Kills MRSA
   - Kills Methicillin Resistant Staph
   - Kills Methicillin Resistant Staphylococcus aureus
   - Kills VRE
   - Kills Vancomycin-resistant Enterococcus
   - Kills Vancomycin resistant Enterococcus faecium
   - Kills HIV
   - Kills Herpes Simplex Virus
   - Kills Influenza A Virus
   - Kills Rhinovirus
   - Kills Polio Virus Type

3. The following optional general marketing phrases have been added:
   - Silver formula
   - Powered by Axenohl (Axenohl, 72977-1, is the MUP diluted to make Axen30)
   - Powered by SDC 2400 (SDC 2400 is an alternate brand name of Axenohl)
   - Powered by [Alternate brand name] (for future additional brand names of the MUP)
   - For daily use
   - Use for a [fresh] [healthier] [home] [environment] [kitchen] [area]
   - Patented formula

This submission is in full compliance with the notification procedure as identified in PR Notice 98-10. As required by PR Notice 98-10 for notification of other labeling revisions, enclosed please find the following:

1. Application Form(8570-1), including the PR Notice 98-10 certification statement
2. One copy of the product labeling with each of the changes highlighted.

Please contact me if you have any questions about the enclosed items. Please fax a copy of the Agency's acceptance of this notification to 619-596-8790.

Sincerely,
EFI H2O

Polana Blount
Regulatory

Axen® 30

Disinfectant, Fungicide & Virucide*

[Disinfects and Deodorizes]
[Restaurants] • [Hospitals] • [Schools] • [Homes] • [Offices]

Manufactured by ETI H2O
A Division of Innovative Medical Services
1725 Gillespie Way
El Cajon, CA 92020
EPA REG. No. 72977-3
EPA EST. No. 72977-CA-001
Net Vol. 32 oz.

Active Ingredient	
Silver[1]	0.003%
Citric Acid	4.840%
Other Ingredients	95.157%
Total	100.000%

[1] Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

[CAUTION]

Note: This product is a Category IV not requiring a signal word. The signal word CAUTION may be used should the registrant or any sub registrant wish.

NOTE: Bracketed information is optional wording for product specific labels

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is a colorless, odorless broad spectrum antimicrobial disinfectant and deodorizer. Proven to kill bacteria, fungus and viruses*, **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** should be used on non-porous environmental hard surfaces in [homes], [hospitals], [nursing] [homes], [medical and dental clinics], [laboratories], [ambulance and patient transfer vehicles], [funeral homes], [hotels], [restaurants], [schools], [day care facilities], [offices], [veterinary clinics], [animal shelters], [kennels], [exercise facilities], [beauty and barber shops], [subways], [trains], [airplanes], [ships], [busses] and [other public transportation vehicles], [locker rooms], [kitchens] and [restrooms].

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray has been formulated to disinfect hard, non-porous environmental surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain) and objects including [walls], [floors], [counters], [sinks], [exterior toilet surfaces], [cabinets], [tubs], [showers], [doorknobs], [lights switch covers], [telephones], [appliances], [stove tops], [bed frames], [wheelchairs], [over-bed tables], [examination tables] and [waste containers], [tables], and [chairs].

[This product] can be used in can be used in [homes], [schools], [nurseries], [daycare centers], [playrooms], [playground *and/or recreational facilities*], [washrooms], [kitchens], [*restrooms and/or bathrooms*], [school buses].

Use to disinfect the following hard, non-porous surfaces: [children's toys], [toys] [toy box(s)], [diaper pail(s)], [diaper changing table(s)], [bathroom and/or kitchen counter(s)], [desk(s)], [play table(s)], [computer keyboard], [telephone] [doorknob(s)], [jungle gym(s)], [playhouse(s)], [child car seat], [stroller(s)],[crib(s)], [playpen(s)], [activity center(s)], [tanning beds];

[FAST], [EASY], [EFFECTIVE]
General Information

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray successfully killed the following organisms under AOAC protocols (In order to ensure that all organisms listed are killed, you must use the contact times as directed in the Application Instructions):

Organism	Kill Time
‡*Pseudomonas aeruginosa* [1]	30 seconds
‡*Staphylococcus aureus* [1]	30 seconds
‡*Salmonella choleraesuis* [1]	30 seconds
‡*Listeria monocytogenes* [1]	30 seconds
Vancomycin resistant *Enterococcus faecium* [1]	2 minutes
Methicillin resistant *Staphylococcus aureus* [1]	2 minutes
Escherichia coli 0157:H7 [1]	2 minutes
Trichophyton mentagrophytes (Athlete's Foot Fungus)	10 minutes
‡**HIV* type 1- Strain HTLV IIIB [1]	30 seconds
*Herpes Simplex Type 1 VR-733 F(1) Strain [2]	1 minute
*Influenza A VR-544, Hong Kong strain [2]	10 minutes
*Rhinovirus R37 VR-1147, Strain 151-1 [2]	10 minutes
*Polio Type 2, VR-1002, Lansing Strain [2]	10 minutes

1 Evaluated in the presence of 5% organic soil.
2 Evaluated in the presence of 1% organic soil

NOTE: Bracketed information is optional wording for product specific labels

[**Fungicidal Activity: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** is effective against *Trichophyton mentagrophytes*, the Athlete's foot fungus, Use in locker rooms, dressing rooms, shower and bath areas, and exercise facilities.]

[**Deodorizes: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** reduces annoying odors caused by bacteria. Use to control odors in hospitals, nursing homes, public restrooms, animal kennels and barn stalls. In private homes, use in the kitchen, bathroom, sink rooms and basements.]

APPLICATION INSTRUCTIONS

Pre-clean surfaces prior to using this product.

General Disinfection:
For general disinfection and control of the bacteria *Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella choleraesuis, Listeria monocytogenes,* Vancomycin Resistant *Enterococcus faecium* (VRE), Methicillin Resistant *Staphylococcus aureus* (MRSA) and *Escherichia coli* 0157:H7 the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 2 minutes. The surface may then be wiped dry with a clean towel. When used as directed, **AXEN® 30™ Disinfectant, Fungicidal & Virucidal Spray** provides protection from *Pseudomonas aeruginosa, Staphylococcus aureus* and *Salmonella choleraesuis* up to 24 hours after initial application.

Fungus Control:
For effective control of the fungus *Trichophyton mentagrophytes*, the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel. Re-apply when cleaning or when new growth appears.

***Viral Control:**
To kill Herpes Simplex Type 1 F(1) Strain Influenza A Virus, Hong Kong strain, Rhinovirus R37 Strain 151-1, Polio Virus Type 2 Lansing Strain the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel

Kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV): **Instructions for Cleaning and Decontamination Against HIV** on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids: **Personal Protection:** When handling items soiled with blood or body fluids, use appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** Apply **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** to area to be treated. The surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 30 seconds. The surface may then be wiped dry with a clean towel. This contact time will not control all organisms listed on this label. Refer to application instructions for other organisms. **Disposal of Infectious Materials:** Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

KEY: The following language will be printed on the label of products intended to be sold to health facilities:

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the human body, either into or in contact with the bloodstream, or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not normally penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

STORAGE AND DISPOSAL	
Storage:	Do not contaminate water, food or feed by storage or disposal.
Disposal:	Do not reuse container. Rinse thoroughly before discarding in trash or recycling.

IN CASE OF EMERGENCY
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact CHEMTREC 1-800-424-9300 for emergency medical treatment information.

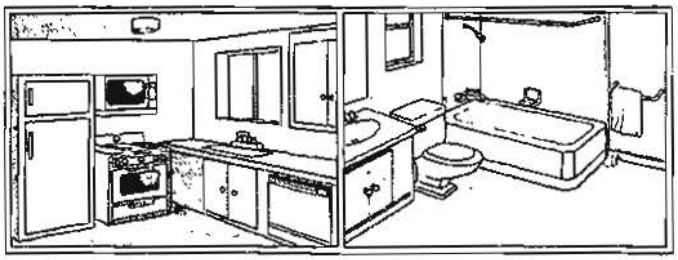
Additional language for front or back panel

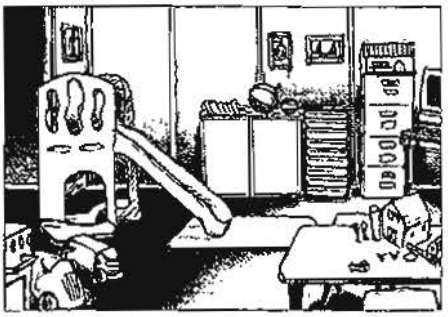
Kills *Staphylococcus aureus* in 30 seconds‡
Kills *Salmonella choleraesuis* in 30 seconds‡
Kills *Listeria monocytogenes* in 30 seconds‡
Kills *Pseudomonas aeruginosa* in 30 seconds‡
Kills germs in 30 seconds‡
Kills common household germs
Kills common household germs including *Salmonella, Staphylococcus, Listeria,* and *E. coli.*
Kills [*Salmonella*], [*Staphylococcus*], [*Listeria*], and [*E. coli*].
Kills - Bacteria, Fungus and Virus*
No dulling residue
Disinfects without bleaching
No harsh chemical smell
Odorless
Disinfects household surfaces
No Mixing Required
[Kills] [Eliminates] MRSA
[Kills] [Eliminates] Methicillin Resistant Staph
[Kills] [Eliminates] Methicillin Resistant *Staphylococcus aureus*
[Kills] [Eliminates] VRE
[Kills] [Eliminates] Vanocomycin-resistant Enterococcus
[Kills] [Eliminates] Vancomycin resistant Enterococcus faecium
[Kills] [Eliminates] HIV
[Kills] [Eliminates] Herpes Simplex Virus
[Kills] [Eliminates] Influenza A Virus
[Kills] [Eliminates] Rhinovirus
[Kills] [Eliminates] Polio Virus Type
Silver Formula
Powered by Axenohl
Powered by SDC 2400
Powered by [Axenohl Alternate brand name]
For daily use
Patented formula
Use for a [fresh] [healthier] [home] [environment] [kitchen]

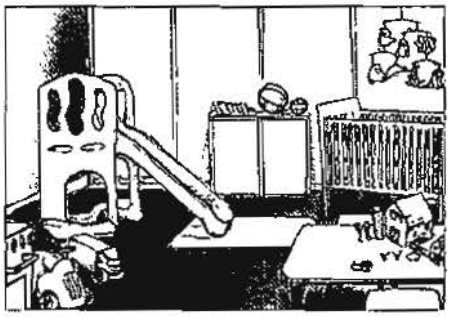
KEY:
*** = Refer to viruses**
‡ = Refer to organisms controlled with 30 second kill time

Alternate language for the front or back panel
[Formulated for] [Hospitality Environment] [Institutional] [Childcare Environments] [Medical & Nursing Environment]

Optional graphics for back of label (graphics are larger here than they will appear on the label)







Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[✓] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
72977-3	Adam Heyward	[✓] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Axen 30		

5. Name and Address of Applicant *(Include ZIP Code)*

ETI H2O
1725 Gillespie Way
El Cajon CA 92020

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below
[ ] Resubmission in response to Agency letter dated _____
[●] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of Other Labeling Revisions per PR Notice 98-10
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [✓] No	[ ] Yes [✓] No	[ ] Yes [✓] No	[ ] Metal [✓] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
● *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[✓] Label [ ] Container	4-32 oz, 1-220 gallon	[ ]

6. Manner in Which Label is Affixed to Product: [✓] Lithograph [✓] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Dolana Blount	Director of Regulatory Affairs	619-596-8600

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
Dolana Blount	Regulatory Director	
4. Typed Name	**5. Date**	
Dolana Blount	02/10/2006	

Please Read All Instructions Before Completing this Form *(Form must be typed)* **Form Approved. OMB No. 2070-0044. Approval Expires 1-31-95**

United States
Environmental Protection Agency
Office of Pesticide Programs (7505C)
Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product	Distributor Company Number
72977-3	83062

Note: Do not submit distributor product labels

Name of Registered Product *(basic product name accepted by EPA)*	Distributor Product Name
Axen 30	Freight Free

Name and Address of Distributor *(Type; include ZIP code)*

Enviroguard Sciences LLC
4725 East 91st Street
Suite 200
Tulsa, OK 74137

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...","distributed by..."; or "sold by..." to show that the name is not that of the manufacturer
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice

Signature and Title of Distributor: [signature], Partner

Date: 1-26-06

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice

Signature and Title of Registrant: [signature], REGULATORY DIRECTOR

Date: 01.27.06

EPA Form 8570-5 (Rev. 8-94) Previous editions are obsolete. White - EPA

Please Read All Instructions Before Completing this Form *(Form must be typed)* **Form Approved. OMB No. 2070-0044. Approval Expires 1-31-95**

United States

Environmental Protection Agency

Office of Pesticide Programs (7505C)
Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

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If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product	Distributor Company Number
72977-3	83062

Note: Do not submit distributor product labels

Name of Registered Product *(basic product name accepted by EPA)*	Distributor Product Name
Axen 30	Staph Attack

Name and Address of Distributor *(Type; include ZIP code)*

Envirogaard Sciences, LLC
4725 East 91st Street
Suite 200
Tulsa, OK 74137

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...","distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor — Date: 1-23-04.

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant: DIRECTOR OF REGULATORY — Date: 01 24 2004

EPA Form 8570-5 (Rev. 8-94) Previous editions are obsolete. White - EPA

Please Read All Instructions Before Completing this Form *(Form must be typed)* Form Approved. OMB No. 2070-0044. Approval Expires 1-31-95

United States
Environmental Protection Agency
Office of Pesticide Programs (7505C)
Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product	Distributor Company Number
72977-3	83062

Note: Do not submit distributor product labels

Name of Registered Product *(basic product name accepted by EPA)*	Distributor Product Name
Axen 30	EnviroGuard

Name and Address of Distributor *(Type; include ZIP code)*
Enviroguard Sciences, LLC
4725 East 91st Street
Suite 200
Tulsa, Oklahoma 74137

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...","distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor: [signature] Partner

Date: 12/21/05

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant: [signature] DIR. OF REGULATORY

Date: 01.03.2006

EPA Form 8570-5 (Rev. 8-94) Previous editions are obsolete. White - EPA

Please Read All Instructions Before Completing this Form *(Form must be typed)* Form Approved. OMB No. 2070-0044. Approval Expires 1-31-96

United States

Environmental Protection Agency

Office of Pesticide Programs (7505C)
Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

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This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product	Distributor Company Number
72977-3	82841

Note: Do not submit distributor product labels

Name of Registered Product *(basic product name accepted by EPA)*	Distributor Product Name
Axen 30	Clean Kill 30

Name and Address of Distributor *(Type; include ZIP code)*

Gateway Oklahoma Trading Corporation
2501 E. Memorial Road
Edmond, OK 73013

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...","distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor: Jerry Edwards, President/CEO

Date: 10-7-05

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant: Julana Bell, Director of Regulatory Affairs

Date: 10-11-05

EPA Form 8570-5 (Rev. 8-94) Previous editions are obsolete. 1 White - EPA

Please Read All Instructions Before Completing this Form *(Form must be typed)* Form Approved. OMB. No. 2070-0044

United States
Environmental Protection Agency
Office of Pesticide Programs (7505C)
Washington, DC 20460

EPA

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product	Distributor Company Number
72977-3	72854

Note: Do not submit distributor product labels

Name of Registered Product *(basic product name accepted by EPA)*	Distributor Product Name
Axen 30	AgION Silver Disinfectant and Virucide™

Name and Address of Distributor *(Type; include ZIP code)*

AgION Technologies, Inc.
60 Audubon Road
Wakefield, MA 01880

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...","distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor: Paul C Ford Corporate Counsel — Date: September 12, 2005

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant: Dir. of Regulatory Affairs — Date: 09/13/2005

EPA Form 8570-5 (Rev. 8-94) Previous editions are obsolete. White - EPA

Please Read All Instructions Before Completing this Form *(Form must be typed)* Form Approved. OMB No. 2070-0044. Approval Expires 1-31-95

United States
Environmental Protection Agency
Office of Pesticide Programs (7505C)
Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product	Distributor Company Number
72977-3	066243

Note: Do not submit distributor product labels

Name of Registered Product *(basic product name accepted by EPA)*	Distributor Product Name
Axen 30	Germ Control 24 - Silver Formula

Name and Address of Distributor *(Type; include ZIP code)*

CLEAN CONTROL CORP
5145 FOREST RUN TRACE-SUITE B
ALPHARETTA, GA 300224504

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...","distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor: [signature] President

Date: 8-12-04

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant: [signature] President

Date: 8/12/04

EPA Form 8570-5 (Rev. 8-94) Previous editions are obsolete. White - EPA

TASK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

A	Completed by Product Manager		
PRODUCT REVIEWER: ADAM HEYWARD			RMB II TEAM 34
Description of Action: Please change to 352296			EPA File Symbol/Reg No.: 72977-3
Decision No. ~~351814~~ 352296 Submission No. 771504			Fee for Service Action Code:
FQPA Action Code: 302	Non-FQPA Action Code:		Fee for Service Fee: $
	MONTH	DAY	YEAR
APPLICATION DATE	11	30	2004
EPA PIN DATE	12	01	2004
REVIEWER ASSIGNED DATE	12	08	2004
DATE DUE TO PM			2005
DATE DUE OUT OF AGENCY			2005

Type of Data:	PSB Product Chemistry ☐	PSB Acute Toxicology ☐	PSB Efficacy ☐	RASSB Environmental Fate ☐	RASSB Ecological Effects ☐	RASSB Chronic Toxicology ☐	RASSB Exposure ☐

COMMENTS: NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM.

DP Barcode No(s):

B	For Arctic Slope Contract Only		
Contractor: Arctic Slope		Contract No.: 0332	ARCTIC SLOPE/MANAGER
Draft Task: Signature _____ _____ (Est. hrs)		Final Task: Signature _____ _____ (Total hrs)	

C	Reviewer's Comments:

Response Code: 17	Response Date: 12/29/04

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 29, 2004

Ms. Dolana Blount
Regulatory Affairs
ETI H220
1725 Gillespie Way
El Cajon, CA 92020

Subject: **AXEN 30**
EPA Registration No. 72977-3
Application Date: November 30, 2004
Receipt Date: December 1, 2004

Dear Ms. Blount:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

- minor label revisions imposed by the California Dept. of Pesticide Registration.

General Comments

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422.

Sincerely,

Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

November 30, 2004

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attention: Adam Heyward

NOTIFICATION
Date Reviewed: 12-29-04
Reviewed By: A. Heyward

Subject: **Axen30, EPA Reg. No. : 72977-3**
Notification of other labeling revisions per PR Notice 98-10

Dear Mr. Heyward:

We are notifying of the following changes to the above referenced master label in response to mandatory label changes imposed by the California Department of Pesticide Registration:

1. Pre-cleaning instructions have read changed to read: "Pre-clean surfaces prior to using this product."

2. The following phrase has been added to the "Contact Time" section of the HIV instructions: "This contact time will not control all organisms listed on this label. Refer to application instructions for other organisms."

3. The term "toilets" has been replaced with "exterior toilet surfaces."

4. The symbol after the term "viruses" and "virucidal" remains an asterisk (*) and identifies the viruses controlled by this product. The symbol after the term "Kills germs in 30 seconds" and related phrases has been changed to a double-dagger (‡) and identifies those organisms that have a kill time of 30 seconds.

This submission is if full compliance with the notification procedure as identified in PR Notice 98-10. As required by PR Notice 98-10 for notification of other labeling revisions, enclosed please find the following:

1. Application Form(8570-1), including the PR Notice 98-10 certification statement
2. One copy of the product labeling with each of the changes highlighted.

Please contact me if you have any questions about the enclosed items. Please fax a copy of the Agency's acceptance of this notification to 619-596-8700.

Sincerely,
ETI H2O

Dolana Blount
Regulatory

1725 Gillespie Way • El Cajon, CA 92020 • telephone 619-596-8600 • facsimile 619-596-8700

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
72977-3	Adam Heyward	☑ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
Axen 30	33	

5. Name and Address of Applicant *(Include ZIP Code)*

ETI H2O
1725 Gillespie Way
El Cajon CA 92020

☐ *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
● Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

NOTIFICATION
Date Reviewed: 12-29-04
Reviewed By: A. Heyward

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of Other Labeling Revisions per PR Notice 98-10.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 4CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to the EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action under sections 12 and 14 of FIFRA

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☑ No	☐ Yes ☑ No	☐ Yes ☑ No	☐ Metal ☑ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
● *Certification must submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☑ Label ☐ Container	4-32 oz.; 1-250 gallon	☑ On label

6. Manner in Which Label is Affixed to Product: ☑ Lithograph ☑ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Dolana Blount	Regulatory	619-596-8600 x 105

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
Dolana Blount	Regulatory	Dolana Blount	November 30, 2004

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Axen® 30

Disinfectant, Fungicide & Virucide*

[Disinfects and Deodorizes]
[Restaurants] • [Hospitals] • [Schools] • [Homes] • [Office

NOTIFICATION
Date Reviewed: 12-29-04
Reviewed By:

Active Ingredient	
Silver[1]	0.003%
Citric Acid	4.840%
Other Ingredients	95.157%
Total	100.000%

[1] Electrolytically generated Silver ions

Axen® 30

Disinfectant, Fungicide & Virucide*

[Disinfects and Deodorizes]
[Restaurants] • [Hospitals] • [Schools] • [Homes] • [Offices]

Manufactured by ETI H2O
A Division of Innovative Medical Services
1725 Gillespie Way
El Cajon, CA 92020
EPA REG. No. 72977-3
EPA EST. No. 72977-CA-001
Net Vol. 32 oz.

Active Ingredient	
Silver[1]	0.003%
Citric Acid	4.840%
Other Ingredients	95.157%
Total	100.000%

[1] Electrolytically generated Silver ions.

KEEP OUT OF REACH OF CHILDREN

CAUTION

NOTE: Bracketed information is optional wording for product specific labels

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is a colorless, odorless broad spectrum antimicrobial disinfectant and deodorizer. Proven to kill bacteria, fungus and viruses*, **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** should be used on non-porous environmental hard surfaces in [homes], [hospitals], [nursing] [homes], [medical and dental clinics], [laboratories], [ambulance and patient transfer vehicles], [funeral homes], [hotels], [restaurants], [schools], [day care facilities], [offices], [veterinary clinics], [animal shelters], [kennels], [exercise facilities], [beauty and barber shops], [subways], [trains], [airplanes], [ships], [busses] and [other public transportation vehicles], [locker rooms], [kitchens] and [restrooms].

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray has been formulated to disinfect hard, non-porous environmental surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain) and objects including [walls], [floors], [counters], [sinks], [exterior toilet surfaces], [cabinets], [tubs], [showers], [doorknobs], [lights switch covers], [telephones], [appliances], [stove tops], [bed frames], [wheelchairs], [over-bed tables], [examination tables] and [waste containers], [tables], and [chairs].

[This product] can be used in can be used in [homes], [schools], [nurseries], [daycare centers], [playrooms], [playground and/or recreational facilities], [washrooms], [kitchens], [restrooms and/or bathrooms], [school buses].

Use to disinfect the following hard, non-porous surfaces: [children's toys], [toys] [toy box(s)], [diaper pail(s)], [diaper changing table(s)], [bathroom and/or kitchen counter(s)], [desk(s)], [play tables(s)], [computer keyboard], [telephone] [doorknob(s)], [jungle gym(s)], [playhouse(s)], [child car seat], [stroller(s)],[crib(s)], [playpen(s)], [activity center(s)], [tanning beds];

FAST, EASY, EFFECTIVE
General Information

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray successfully killed the following organisms under AOAC protocols (In order to ensure that all organisms listed are killed, you *must use the contact times as directed in the Application Instructions):*

Organism	Kill Time
‡*Pseudomonas aeruginosa* [1]	30 seconds
‡*Staphylococcus aureus* [1]	30 seconds
‡*Salmonella choleraesuis* [1]	30 seconds
‡*Listeria monocytogenes* [1]	30 seconds
Vancomycin resistant *Enterococcus faecium* [1]	2 minutes
Methicillin resistant *Staphylococcus aureus* [1]	2 minutes
Escherichia coli 0157:H7 [1]	2 minutes
Trichophyton mentagrophytes (Athlete's Foot Fungus)	10 minutes
‡**HIV* type 1- Strain HTLV IIIB [1]	30 seconds
*Herpes Simplex Type 1 VR-733 F(1) Strain [2]	1 minute
*Influenza A VR-544, Hong Kong strain [2]	10 minutes
*Rhinovirus R37 VR-1147, Strain 151-1 [2]	10 minutes
*Polio Type 2, VR-1002, Lansing Strain [2]	10 minutes

1 Evaluated in the presence of 5% organic soil.
2 Evaluated in the presence of 1% organic soil

NOTE: Bracketed information is optional wording for product specific labels

Fungicidal Activity: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is effective against *Trichophyton mentagrophytes*, the Athlete's foot fungus, Use in locker rooms, dressing rooms, shower and bath areas, and exercise facilities.

Deodorizes: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray reduces annoying odors caused by bacteria. Use to control odors in hospitals, nursing homes, public restrooms, animal kennels and barn stalls. In private homes, use in the kitchen, bathroom, sink rooms and basements.

APPLICATION INSTRUCTIONS

Pre-clean surfaces prior to using this product.

General Disinfection:
For general disinfection and control of the bacteria *Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella choleraesuis, Listeria monocytogenes,* Vancomycin Resistant *Enterococcus faecium* (VRE), Methicillin Resistant *Staphylococcus aureus* (MRSA) and *Escherichia coli* 0157:H7 the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 2 minutes. The surface may then be wiped dry with a clean towel. When used as directed, **AXEN® 30™ Disinfectant, Fungicidal & Virucidal Spray** provides protection from *Pseudomonas aeruginosa, Staphylococcus aureus* and *Salmonella choleraesuis* up to 24 hours after initial application.

Fungus Control:
For effective control of the fungus *Trichophyton mentagrophytes*, the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel. Re-apply when cleaning or when new growth appears.

*Viral Control:
To kill Herpes Simplex Type 1 F(1) Strain Influenza A Virus, Hong Kong strain, Rhinovirus R37 Strain 151-1, Polio Virus Type 2 Lansing Strain the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel

Kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV): **Instructions for Cleaning and Decontamination Against HIV** on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids: **Personal Protection:** When handling items soiled with blood or body fluids, use appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** Apply **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** to area to be treated. The surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 30 seconds. The surface may then be wiped dry with a clean towel. This contact time will not control all organisms listed on this label. Refer to application instructions for other organisms. **Disposal of Infectious Materials:** Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

KEY: The following language will be printed on the label of products intended to be sold to health facilities:

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the human body, either into or in contact with the bloodstream, or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not normally penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

STORAGE AND DISPOSAL	
Storage:	Do not contaminate water, food or feed by storage or disposal.
Disposal:	Do not reuse container. Rinse thoroughly before discarding in trash or recycling.

IN CASE OF EMERGENCY
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact CHEMTREC 1-800-424-9300 for emergency medical treatment information.

Additional language for front panel

Kills *Staphylococcus aureus* in 30 seconds‡
Kills *Salmonella choleraesuis* in 30 seconds‡
Kills *Listeria monocytogenes* in 30 seconds‡
Kills *Pseudomonas aeruginosa* in 30 seconds‡
Kills germs in 30 seconds‡
Kills common household germs
Kills common household germs including *Salmonella, Staphylococcus, Listeria,* and *E. coli.*
Kills *Salmonella, Staphylococcus, Listeria,* and *E. coli.*
Kills - Bacteria, Fungus and Virus*
No dulling residue
Disinfects without bleaching
No harsh chemical smell
Odorless
Disinfects household surfaces
No Mixing Required

KEY:
*** = Refer to viruses**
‡ = Refer to organisms controlled with 30 second kill time

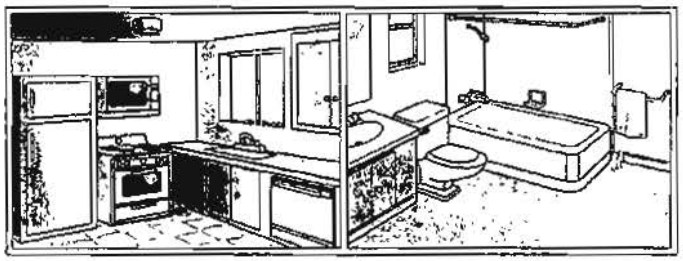
Alternate language for the back panel

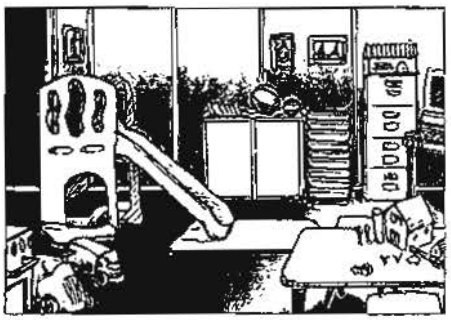
Kills *Staphylococcus aureus* in 30 seconds‡
Kills *Salmonella choleraesuis* in 30 seconds‡
Kills *Listeria monocytogenes* in 30 seconds‡
Kills *Pseudomonas aeruginosa* in 30 seconds‡
Kills germs in 30 seconds‡

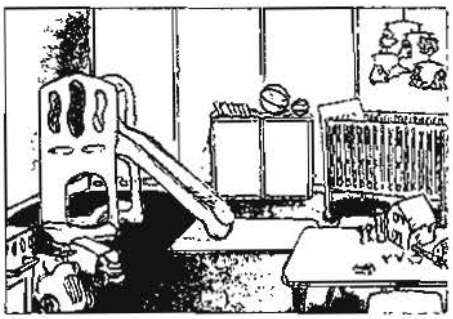
*** = Refer to viruses**
‡ = Refer to organisms controlled with 30 second kill time

Alternate language for the front or back panel
Hospitality Environment
Institutional
Childcare Environments
Medical & Nursing Environment

Optional graphics for back of label (graphics are larger here than they will appear on the label)







UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

November 16, 2004

Andrew Yokoyama
Senior Pesticide Use Specialist
Dept. of Pesticide Regulation
Pesticide Registration Branch
916-324-3914
ayokoyama@cdpr.ca.gov

Subject: AXEN® 30
EPA Registration Number 72977-3

Dear Mr. Yokoyama:

This is response to your email question with regards to the current accepted label dated March 17, 2003 for the subject product. The label contains the EPA efficacy laboratory established contact time and a chart which display the actual kill time for each bacteria and viruses. The label dated March 17. 2003 is a legal accepted label. You may use the March 17, 2003-label to complete the processing of AXEN® 30, EPA Registration Number 72977-3.

Residual claims are listed on the current Elizabeth Brown <brown@chemreg.com> label against some bacteria. Per the label, "AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray provides protection from *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella choleraesuis* up to 24 hours after initial application." The Agency has requested that the residual claims be removed from the label (March 3, 2003). The last accepted label still makes reference to residual efficacy. The registrant was again told, via telephone communication on November 15, that the residual claim must be deleted from the label within six (6) month from date of notice, along with other label revisions, e.g., chart. I will follow-up this with a written letter to the company.

Innovative Medical Services has also agreed to meet with the EPA/AD to discuss the labeling and to revise it so that the label is similar to other EPA registered products that list the actual kill time on the label. Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

Dolana Blount
<dblount@imspure.com>
12/14/2004 06:20 PM

To Adam Heyward/DC/USEPA/US@EPA
cc
bcc
Subject Conference call summary

Adam-

Thank you for your time this morning. I appreciate you rushing from your prior meeting to join us. Below is a brief summary of our conversation and agreement.

Issue 1: Label formatting for kill time vs. official contact time.

As we agreed, we will move the table listing the tested contact times after the application instructions. We will also put the statement, " In order to ensure that all organisms listed are killed, you must use the contact times as directed in the Application Instructions" in bold font. As you stated, this is a formatting issue (non-notification) and does not require submission to the Agency. This will take effect at the next printing of labels.

Issue 2: Residual sanitization claim

As agreed, we will submit a written justification as to why the residual protection study we submitted should be accepted for the existing claim. The claim can remain on the label until EPA considers that justification.

If you have any questions, please contact me to discuss.

Sincerely,
Dolana Blount
ETI H2O
DBlount@imspure.com
619.596.8600, ext. 105

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 6, 2004

INTERNAL MEMORANDUM

Subject: Response to Multiple Contact Times for EPA Reg. No. 72977-3, Axen® 30 Disinfectant, Fungicide, & Virucide

From: Tajah L. Blackburn, Ph.D., Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

To: Adam Heyward PM 34
Regulatory Management II
Antimicrobials Division (7510C)

Registrant: ETI H2O
A Division of Innovative Medical Services
1725 Gillespie Way
El Cajon, CA 92020

Formulation from Label

Active Ingredient(s)	% by wt.
Silver	0.003%
Citric Acid	4.840%
Other Ingredients	95.157%
Total	100.000%

Comments Pertaining to Label "Kill Time" and "Contact Times"

The last accepted label is dated March 17, 2004. Using the last accepted label as a reference, the chart listed on page 2 detailing kill times is not consistent with the contact times listed for bacteria and viruses. A copy of the chart is listed below:

Organism	Kill Time
Pseudomonas aeruginosa	30 seconds
Staphylococcus aureus	30 seconds
Listeria monocytogenes	30 seconds
Vancomycin resistant *Enterococcus faecium*	2 minutes
Methicillin resistant *Staphylococcus aureus*	2 minutes
Escherichia coli O157:H7	2 minutes
Trichophyton mentagrophytes (Athlete's foot)	10 minutes
HIV-type 1– Strain HTLV IIIB	30 seconds
Herpes Simplex Type 1 VR-733 F(1) Strain	1 minute
Influenza A VR-544, Hong Kong strain	10 minutes
Rhinovirus R37 VR-1147, Strain 151-1	10 minutes
Polio Type 2, VR-1002, Lansing Strain	10 minutes

The heading attached to this chart states that "AXEN® 30 Disinfectant, Fungicidal, & Virucidal spray successfully killed the following organisms under AOAC protocols (**In order to ensure that all organisms listed are killed, you must use the contact times as directed in the Application Instructions).**" The kill times are representative of laboratory observations, and may be misleading to the consumer. The statement attached to the chart, "...you must use the contact times as directed in the Application Instructions," should be placed in bold, or this chart should be revised or deleted. From a semantic standpoint, the consumer may potentially misinterpret the "kill time" for "contact time." To justify the continued presence of chart, the applicant stated that the chart will remain as originally submitted with the statement cited above (letter dated March 10, 2003). The Agency stresses the importance of one contact time for bacteria and one contact time for viruses, if not the same contact time. The last accepted label has a contact time of 2 minutes for bacteria (*Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis*, *Listeria monocytogenes*, Vancomycin Resistant *Entercoccus faecalis* (VRE), Methicillin Resistant *Staphylococcus aureus* (MRSA) and *Escherichia coli* O157:H7), a contact time of 10 minutes for viruses (Herpes Simplex Type 1 F(1) Strain, Influenza A Virus Hong Kong strain, Rhinovirus R37 Strain 151-1, Polio Virus Type 2 Lansing Strain, and a contact time of 30 seconds for Human Immunodeficiency Virus Type 1 (HIV-1) which are currently acceptable.

A residual claims appears to be included against some bacteria. Per the label, "AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray provides protection from *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella choleraesuis* up to 24 hours after initial application." The Agency has requested that the residual claims be removed from the label (March 3, 2003). The last accepted label still makes reference to residual efficacy.

Lastly, the following label change should take place on any subsequent label submissions:

-"*E.coli* 0157:H7" to read "*E.coli* O157:H7".

Dolana Blount
<dblount@imspure.com
>
10/04/2004 02:56 PM

To: Adam Heyward/DC/USEPA/US@EPA, Adam Heyward/DC/USEPA/US@EPA
cc:
Subject: Axen30 EPA Reg#72977-3

RE: Axen30, EPA Reg# 72977-3

Adam-

I understand that you are reviewing our product label in reference to questions from CDPR. I wanted to take this opportunity to remind you that we discussed this issue at the time Axen30 was registered, and it was agreed that we would make a clear notation that the user must follow the contact times listed under application instructions. As you will note, the label currently reads, "In order to ensure that all organisms listed are killed, you must use the contact times as directed in the Application Instructions." The Application Instructions clearly indicate the longest contact time for each subset of microbe (2 minutes for bacteria, 10 minutes for Fungus and viruses listed).

I would like to point out that other registrants also list multiple kill times on their label. Please refer to Product Reg# **1130-15** (Burnshine Germicidal Solution) and Product Reg# **70791-1** (EcoTru). Both of these labels list a range of kill times for various organisms with no disclaimer like ours as indicated above. We feel that we have made every effort to make the label clear to the consumer while accurately reflecting our products performance, and we believe that the label should not be altered as the Agency has allowed other registrants to label their products in a similar way.

Thank you for your attention to this matter. Please feel free to contact me if you have any questions.

Best Regards,

Dolana Blount
ETI H2O
DBlount@imspure.com
619.596.8600, ext. 105

****

PM WORK ASSIGNMENT SHEET

DECISION 350354 PM 34

DESCRIPTION OF ACTION: _____

SUBMISSION BAR CODE: S 942178

PRODUCT REVIEWER: Lisa

FILE SYMBOL/REG NO.: 72977-3

FQPA ACTION CODE: 303 NON-FQPA ACTION CODE: _____

AMOUNT OF TIME TO COMPLETE TASK (ASRC only)	HOURS _____

	MONTH	DAY	YEAR
APPLICATION DATE	05	22	03
EPA PIN DATE	07	09	03
REVIEWER ASSIGNED DATE	07	09	03

TYPE OF DATA

Product Chemistry: ☐ Product Toxicology: ☐ Efficacy: ☐

RASSB: ☐ HED TOX ☐ ENVIRONMENTAL FATE ☐ FISH/WILDLIFE ☐

Other ☐ _____

COMMENTS:

PR Notice 2001-1: Review complete label within 30 days from Reviewer

Assignment Date: _____.

Reviewed by: _____

Gold Seal

JACKET(S)/FILE SHOULD BE SUBMITTED WITH YOUR LETTERS FOR SIGNATURE

RESPONSE CODE: 17 RESPONSE DATE: 09 / 22 / 03
MO Day Year

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 23, 2003

I, Adam Heyward, Regulatory Management Branch II, Antimicrobials Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify that the pesticide product listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter

Registration of this product with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

EPA has issued a registration number for the product listed below to.

ETI H2O
a division of Innovative Medical Services
1725 Gillespie Way
El Cajon, CA 92020

EPA Registration Number:	72977-3
Name of Product:	Axen 30

Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

VIA FACSMILIE
(703) 308-6467

May 22, 2003

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510C)
US EPA
Washington, DC

Dear Mr. Heyward:

ETI H2O is requesting a certified letter in reference to our registered product, Axen 30 (**72977-3**). Please address the letter to Innovative Medical Services, 1725 Gillespie Way, El Cajon, CA 92020.

Should you have any questions, or require additional information, please do not hesitate to contact me directly.

Thank you,
ETI H2O

Dolana Blount
Assistant to the President

FAX COVER

DATE: 05-22-03

TO: Adam Heyward
USEPA, Antimicrobial Division

FAX: (703) 308-6467

FROM: Dolana Blount
ETI H2O
PHONE: (619) 596-8600 Ext. 105
FAX: (619) 596-8700

MESSAGE:

Adam:
I was told that I should direct this request to you; however, if someone else at the agency is responsible for producing this letter, please direct my request to him or her.

Thank you-
Dolana Blount

Page 1 of 2

FAX COVER

DATE: 07.09.03

TO: Adam Heyward
US EPA, Antimicrobial Division

FAX: (703) 308-6467

FROM: Dolana Blount
ETI H2O
PHONE: (619) 596-8600 Ext. 105
FAX: (619) 596-8700

MESSAGE:

Page 1 of 4

1725 Gillespie Way · El Cajon, CA 92020 · voice (619) 596-8600 · fax (619) 596-8700

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 1, 2003

Ms. Dolana Blount
Senior Mircrobiologist
ETI H20
A division of Innovative Medical Services
1725 Gillespie Way
El Cajon, CA 92020

Subject: Notification Application Per PR Notice 98-10
Axen 30
EPA Registration No.72977-3
Application Dated March 28, 2003

Dear Ms. Blount:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification:

- alternate brand names:

  - Clean Kill 30

General Comment:

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable. A copy of the notification has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422, or Lisa McKelvin at (703) 308-7496.

Sincerely,

Lisa McKelvin

Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

601 SOUTH LINCOLN AVENUE
STERLING, VA 20164-2024
Phone: (703) 471-6560
Fax: (703) 471-6299

LAIRD'S REGULATORY CONSULTANTS, INC.
Over 32 years of pesticidal experience

Fax

To:	Adam Heyward	From:	Olivia D. Laird
Fax:	(703) 308-8486	Date:	June 12, 2003
Phone:	(703) 308-8422	Pages:	3
Re:	Additional Brand Name Notification	CC:	

X Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

•Comments:

Adam:

Attached is the Application for amendment which was delivered in March. Per our conversation you stated that you didn't receive it so I am herewith forwarding you a copy. The original delivery was just submitted as an amendment we have checked off Notification on it this time and the certification statement is included.

Thank you,

Olivia D. Laird

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*		
Name	Title	Telephone No. (Include Area Code)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature	3. Title	
4. Typed Name For Dotonna Bloom	5. Date 3/28/03	

EPA Form #570-1 (Rev. 3-94) Previous editions are obsolete.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
72977-3	Adam Heyward	☑ None ☐ Restricted
4. Company/Product (Name)	PM#	
Axen 30	34	

5. Name and Address of Applicant *(Include ZIP Code)*

ETI H2O
a division of Innovative Medical Services
1725 Gillespie Way, El Cajon CA 92020

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☒ Modification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☑ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Additional Brand Name registration :

Clean Kill 30

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☑ No	☐ Yes ☑ No	☐ Yes ☑ No	☐ Metal ☑ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☑ Label ☐ Container	5, 16, 32 oz.; 1.5,55,250 gallon	

6. Manner in Which Label Is Affixed to Product: ☑ Lithograph ☑ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

8. Date Application Received (Stamped)

2. Signature	3. Title
4. Typed Name	5. Date
For Debra Bloom	3/28/03

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

INNOVATIVE MEDICAL SERVICES
a NASDAQ company

March 28, 2003

Re: Axen 30™, EPA Reg. # 72977-3
Additional Brand Name: Clean Kill 30™

CERTIFICATION STATEMENT

Notification of Additional Brand Name per PR Notice 98-10.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and Innovative Medical Services may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Sincerely,
INNOVATIVE MEDICAL SERVICES

Dolana Blount
Senior Microbiologist

1725 Gillespie Way • El Cajon, CA 92020 • Voice (619) 596-8600 • Facsimile (619) 596-8700

INNOVATIVE MEDICAL SERVICES
a NASDAQ company

March 28, 2003

Re: Axen 30™, EPA Reg. # 72977-3
Additional Brand Name: Clean Kill 30™

CERTIFICATION STATEMENT

Notification of Additional Brand Name per PR Notice 98-10.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and Innovative Medical Services may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Sincerely,
INNOVATIVE MEDICAL SERVICES

Dolana Blount
Senior Microbiologist

1725 Gillespie Way • El Cajon, CA 92020 • Voice (619) 596-8600 • Facsimile (619) 596-8700

Please Read All Instructions Before Completing this Form (Form must be typed) Form Approved. OMB No. 2070-0044. Approval Expires 1-31-95

United States
Environmental Protection Agency
Office of Pesticide Programs (7505C)
Washington, DC 20460

289337

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and it must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product	Distributor Company Number
72977-3 4	69268

Note: Do not submit distributor product labels

Name of Registered Product (basic product name accepted by EPA)	Distributor Product Name
Axen 30	Critical Care 74

Name and Address of Distributor (Type; include ZIP code)

Envirox
1938 E. Fairchild Street
Danville, IL 61832-2317

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...","distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor — Date: 4/16/03

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant — Date: 04.15.03

EPA Form 8570-5 (Rev. 8-94) Previous editions are obsolete. 1 White - EPA

5.12.2003

Axen® 30

Disinfectant, Fungicide & Virucide*

Disinfects and Deodorizes
Restaurants • Hospitals • Schools • Homes • Offices

Manufactured by ETI H2O
A Division of Innovative Medical Services
1725 Gillespie Way
El Cajon, CA 92020
EPA REG. No. 72977-3
EPA EST. No. 72977-CA-001
Net Vol. 32 oz.

Active Ingredient	
Silver[1]	0.003%
Citric Acid	4.840%
Other Ingredients	95.157%
Total	100.000%

[1] Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

CAUTION

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is a colorless, odorless broad spectrum antimicrobial disinfectant and deodorizer. Proven to kill bacteria, fungus and viruses*, **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** should be used on non-porous environmental hard surfaces in homes, hospitals, nursing homes, medical and dental clinics, laboratories, ambulance and patient transfer vehicles, funeral homes, hotels, restaurants, schools, day care facilities, offices, veterinary clinics, animal shelters, kennels, exercise facilities, beauty and barber shops, subways, trains, airplanes, ships, busses and other public transportation vehicles, locker rooms, kitchens and restrooms.

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray has been formulated to disinfect hard, non-porous environmental surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain) and objects such as walls, floors, counters, sinks, toilets, cabinets, tubs, showers, doorknobs, lights switch covers, telephones, appliances, stove tops, bed frames, wheelchairs, over-bed tables, examination tables and waste containers, tables, and chairs.

FAST, EASY, EFFECTIVE
General Information

***AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** successfully killed the following organisms under AOAC protocols (In order to ensure that all organisms listed are killed, you must use the contact times as directed in the Application Instructions):

Organism	Kill Time
Pseudomonas aeruginosa [1]	30 seconds
Staphylococcus aureus [1]	30 seconds
Salmonella choleraesuis [1]	30 seconds
Listeria monocytogenes [1]	30 seconds
Vancomycin resistant *Enterococcus faecium* [1]	2 minutes
Methicillin resistant *Staphylococcus aureus* [1]	2 minutes
Escherichia coli 0157:H7 [1]	2 minutes
Trichophyton mentagrophytes (Athlete's Foot Fungus)	10 minutes
HIV type 1- Strain HTLV IIIB [1]	30 seconds
Herpes Simplex Type 1 VR-733 F(1) Strain [2]	1 minute
Influenza A VR-544, Hong Kong strain [2]	10 minutes
Rhinovirus R37 VR-1147, Strain 151-1 [2]	10 minutes
Polio Type 2, VR-1002, Lansing Strain [2]	10 minutes

1 Evaluated in the presence of 5% organic soil.
2 Evaluated in the presence of 1% organic soil

Fungicidal Activity: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is effective against *Trichophyton mentagrophytes*, the Athlete's foot fungus, Use in locker rooms, dressing rooms, shower and bath areas, and exercise facilities.

Deodorizes: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray reduces annoying odors caused by bacteria. Use to control odors in hospitals, nursing homes, public restrooms, animal kennels and barn stalls. In private homes, use in the kitchen, bathroom, sink rooms and basements.

APPLICATION INSTRUCTIONS

Surfaces that are heavy soiled with organic matter must be pre-cleaned prior to using this product.

General Disinfection:

For general disinfection and control of bacteria such as *Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella choleraesuis, Listeria monocytogenes,* Vancomycin Resistant *Enterococcus faecium* (VRE), Methicillin Resistant *Staphylococcus aureus* (MRSA) and *Escherichia coli* 0157:H7 the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 2 minutes. The surface may then be wiped dry with a clean towel. When used as directed, **AXEN® 30™ Disinfectant, Fungicidal & Virucidal Spray** provides protection from *Pseudomonas aeruginosa, Staphylococcus aureus* and *Salmonella choleraesuis* up to 24 hours after initial application.

Fungus Control:
For effective control of fungus such as *Trichophyton mentagrophytes,* the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel. Re-apply when cleaning or when new growth appears.

Viral Control:
To kill Herpes Simplex Type 1 F(1) Strain Influenza A Virus, Hong Kong strain, Rhinovirus R37 Strain 151-1, Polio Virus Type 2 Lansing Strain the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel

Kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV): **Instructions for Cleaning and Decontamination Against HIV** on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids: **Personal Protection:** When handling items soiled with blood or body fluids, use appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** Apply **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** to area to be treated. The surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 30 seconds. The surface may then be wiped dry with a clean towel. **Disposal of Infectious Materials:** Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

KEY: The following language will be printed on the label of products intended to be sold to health facilities:

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the human body, either into or in contact with the bloodstream, or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not normally penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

STORAGE AND DISPOSAL	
Storage:	Do not contaminate water, food or feed by storage or disposal.
Disposal:	Do not reuse container. Rinse thoroughly before discarding in trash or recycling.

IN CASE OF EMERGENCY
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact CHEMTREC 1-800-424-9300 for emergency medical treatment information.

Additional language for front panel

Kills *Staphylococcus aureus* in 30 seconds*
Kills *Salmonella choleraesuis* in 30 seconds*
Kills *Listeria monocytogenes* in 30 seconds*
Kills *Pseudomonas aeruginosa* in 30 seconds*
Kills germs in 30 seconds*
Kills common household germs
Kills common household germs including *Salmonella, Staphylococcus, Listeria*, and *E. coli.*
Kills *Salmonella, Staphylococcus, Listeria*, and *E. coli.*
Kills - Bacteria, Fungus and Virus*
No dulling residue
Disinfects without bleaching
No harsh chemical smell
Odorless
Disinfects household surfaces
No Mixing Required

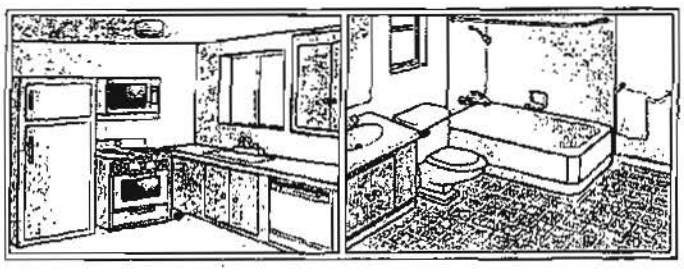
KEY: * = Refer to table

Alternate language for the back panel

Kills *Staphylococcus aureus* in 30 seconds*
Kills *Salmonella choleraesuis* in 30 seconds*
Kills *Listeria monocytogenes* in 30 seconds*
Kills *Pseudomonas aeruginosa* in 30 seconds*
Kills germs in 30 seconds*

KEY: * = Refer to table

Optional graphics for back of label (graphics are larger here than they will appear on the label)



KITCHEN BATHROOM

Laird's Regulatory Consultants, Inc

Over 28 years Experience and Expertise in The Regulation of Pesticide Products

March 26, 2003

Mr. Adam Hayward PM 34
Environmental Protection Agency
Regulatory Management II
Antimicrobial Division (7510C)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Subject: AXEN 30
EPA REG. NO. 72977-3
Final Printed Labels

Dear Mr. Hayward:

Please find attached hereto, two (2) copies of the final printed label in response to you letter dated March 24, 2003. All specified changes have been incorporated.

Thank you for all of your assistance during this process.

Sincerely,

Olivia D. Laird
President/Agent

Olivia D. Laird President/Owner * 501 South Lincoln Avenue, Sterling, VA 20164-2024* Phone 703/471-6890 * Fax 703/471-6269

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
72977-3	Adam Heyward	☑ None ☐ Restricted
4. Company/Product (Name)	PM#	
Axen 30	34	

5. Name and Address of Applicant *(Include ZIP Code)*

ETI H2O
a division of Innovative Medical Services
1725 Gillespie Way, El Cajon CA 92020

☐ *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☑ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Additional Brand Name registration :

Clean Kill 30

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☑ No	☐ Yes ☑ No	☐ Yes ☑ No	☐ Metal ☑ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
* Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☑ Label ☐ Container	5, 16, 32 oz.; 1,5,55,250 gallon	

6. Manner in Which Label is Affixed to Product: ☑ Lithograph ☑ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Jay A Wom	President	703 802 8616

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
for Dolana Blount	Senior Microbiologist
4. Typed Name	5. Date
Dolana Blount	3/28/03

48

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

March 17, 2003

Mr. Michael L. Krall
Consultant Agent
For
Innovative Medical Services
1725 Gillespie Way
El Cajon, California 92020

Dear Mr. Krall:

Subject: **Axen 30**
EPA File Symbol Number 72977-3
Letter Dated March 10, 2003

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable.

A stamped copy of the accepted labeling is enclosed.

If you have any questions concerning this letter, please contact Adam Heyward at (703) 308-6422 or Drusilla Copeland at (703) 308-6224.

Sincerely,

for Drusilla Copeland

Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

enclosure:

	CONCURRENCES							
SYMBOL								
SURNAME								
DATE								

289103

Please Read All Instructions Before Completing this Form *(Form must be typed)* **Form Approved. OMB No. 2070-0044. Approval Expires 1-31-95**

United States

Environmental Protection Agency

Office of Pesticide Programs (7505C)
Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product	Distributor Company Number
72977-3	69268

Note: Do not submit distributor product labels

Name of Registered Product *(basic product name accepted by EPA)*	Distributor Product Name
Axen 30	Critical Care™

Name and Address of Distributor *(Type; include ZIP code)*

Envirox
1938 E Fairchild Street
Danville, IL 61832-2327

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...","distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

Date

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

Date 04.15.03

EPA Form 8570-5 (Rev. 8-94) Previous editions are obsolete.

White - EPA

5-6-2003

Axen® 30

Disinfectant, Fungicide & Virucide*

Disinfects and Deodorizes
Restaurants • Hospitals • Schools • Homes • Offices

Manufactured by ETI H2O
A Division of Innovative Medical Services
1725 Gillespie Way
El Cajon, CA 92020
EPA REG. No. 72977-3
EPA EST. No. 72977-CA-001
Net Vol. 32 oz.

Active Ingredient	
Silver[1]	0.003%
Citric Acid	4.840%
Other Ingredients	95.157%
Total	100.000%

[1] Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

CAUTION

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is a colorless, odorless broad spectrum antimicrobial disinfectant and deodorizer. Proven to kill bacteria, fungus and viruses*, **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** should be used on non-porous environmental hard surfaces in homes, hospitals, nursing homes, medical and dental clinics, laboratories, ambulance and patient transfer vehicles, funeral homes, hotels, restaurants, schools, day care facilities, offices, veterinary clinics, animal shelters, kennels, exercise facilities, beauty and barber shops, subways, trains, airplanes, ships, busses and other public transportation vehicles, locker rooms, kitchens and restrooms.

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray has been formulated to disinfect hard, non-porous environmental surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain) and objects such as walls, floors, counters, sinks, toilets, cabinets, tubs, showers, doorknobs, lights switch covers, telephones, appliances, stove tops, bed frames, wheelchairs, over-bed tables, examination tables and waste containers, tables, and chairs.

FAST, EASY, EFFECTIVE
General Information

***AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** successfully killed the following organisms under AOAC protocols (In order to ensure that all organisms listed are killed, you must use the contact times as directed in the Application Instructions):

Organism	Kill Time
Pseudomonas aeruginosa [1]	30 seconds
Staphylococcus aureus [1]	30 seconds
Salmonella choleraesuis [1]	30 seconds
Listeria monocytogenes [1]	30 seconds
Vancomycin resistant *Enterococcus faecium* [1]	2 minutes
Methicillin resistant *Staphylococcus aureus* [1]	2 minutes
Escherichia coli 0157:H7 [1]	2 minutes
Trichophyton mentagrophytes (Athlete's Foot Fungus)	10 minutes
HIV type 1- Strain HTLV IIIB [1]	30 seconds
Herpes Simplex Type 1 VR-733 F(1) Strain [2]	1 minute
Influenza A VR-544, Hong Kong strain [2]	10 minutes
Rhinovirus R37 VR-1147, Strain 151-1 [2]	10 minutes
Polio Type 2, VR-1002, Lansing Strain [2]	10 minutes

1 Evaluated in the presence of 5% organic soil.
2 Evaluated in the presence of 1% organic soil

Fungicidal Activity: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is effective against *Trichophyton mentagrophytes*, the Athlete's foot fungus, Use in locker rooms, dressing rooms, shower and bath areas, and exercise facilities.

Deodorizes: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray reduces annoying odors caused by bacteria. Use to control odors in hospitals, nursing homes, public restrooms, animal kennels and barn stalls. In private homes, use in the kitchen, bathroom, sink rooms and basements.

APPLICATION INSTRUCTIONS

Surfaces that are heavy soiled with organic matter must be pre-cleaned prior to using this product.

General Disinfection:

For general disinfection and control of bacteria such as *Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella cholerasuis, Listeria monocytogenes,* Vancomycin Resistant *Enterococcus faecium* (VRE), Methicillin Resistant *Staphylococcus aureus* (MRSA) and *Escherichia coli* 0157:H7 the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 2 minutes. The surface may then be wiped dry with a clean towel. When used as directed, **AXEN® 30™ Disinfectant, Fungicidal & Virucidal Spray** provides protection from *Pseudomonas aeruginosa, Staphylococcus aureus* and *Salmonella cholerasuis* up to 24 hours after initial application.

Fungus Control:
For effective control of fungus such as *Trichophyton mentagrophytes*, the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel. Re-apply when cleaning or when new growth appears

Viral Control:
To kill Herpes Simplex Type 1 F(1) Strain Influenza A Virus, Hong Kong strain, Rhinovirus R37 Strain 151-1, Polio Virus Type 2 Lansing Strain the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel

Kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV): **Instructions for Cleaning and Decontamination Against HIV** on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids: **Personal Protection:** When handling items soiled with blood or body fluids, use appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** Apply **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** to area to be treated. The surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 30 seconds. The surface may then be wiped dry with a clean towel. **Disposal of Infectious Materials:** Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

KEY: The following language will be printed on the label of products intended to be sold to health facilities:

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the human body, either into or in contact with the bloodstream, or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not normally penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

STORAGE AND DISPOSAL	
Storage:	Do not contaminate water, food or feed by storage or disposal.
Disposal:	Do not reuse container. Rinse thoroughly before discarding in trash or recycling.

IN CASE OF EMERGENCY
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact CHEMTREC 1-800-424-9300 for emergency medical treatment information.

7377-3

Additional language for front panel

Kills *Staphylococcus aureus* in 30 seconds*
Kills *Salmonella choleraesuis* in 30 seconds*
Kills *Listeria monocytogenes* in 30 seconds*
Kills *Pseudomonas aeruginosa* in 30 seconds*
Kills germs in 30 seconds*
Kills common household germs
Kills common household germs including *Salmonella, Staphylococcus, Listeria*, and *E. coli.*
Kills *Salmonella, Staphylococcus, Listeria*, and *E. coli.*
Kills - Bacteria, Fungus and Virus*
No dulling residue
Disinfects without bleaching
No harsh chemical smell
Odorless
Disinfects household surfaces
No Mixing Required

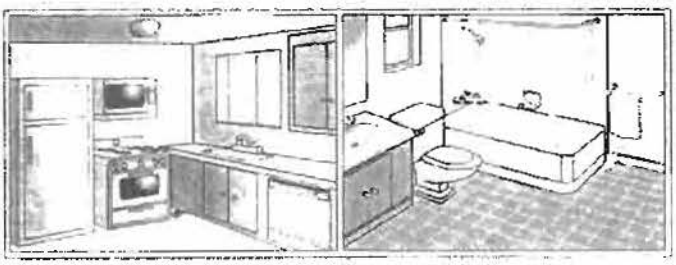
KEY: * = Refer to table

Alternate language for the back panel

Kills *Staphylococcus aureus* in 30 seconds*
Kills *Salmonella choleraesuis* in 30 seconds*
Kills *Listeria monocytogenes* in 30 seconds*
Kills *Pseudomonas aeruginosa* in 30 seconds*
Kills germs in 30 seconds*

KEY: * = Refer to table

Optional graphics for back of label (graphics are larger here than they will appear on the label)



KITCHEN BATHROOM

72977-3

March 10, 2003

Adam Heyward, PM 34
US Environmental Protection Agency
Office of Pesticide Programs
Regulatory Management Branch II
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

SUBJECT Axen30
EPA product Reg. Number 72977-3
Telecom of March 6, and 10, 2003

Dear Mr. Heyward:

Attached are three (3) copies of the revised final printed label bearing the revisions outlined in the March 3, 2003 Registration Notice with the exception of the following modifications as verbally approved by you in our telephone conferences referenced above:

1. The chart will remain as originally submitted and the statement below will be added directly above the chart:
   "In order to ensure that all organisms listed are killed, you must use the contact times as directed in the Application Instructions"

2. The following phrases from the 'Additional Language for Front Panel" have not been removed but have been revised as requested to remove the reference to 99.9999% where applicable:
   - No dulling residue
   - Disinfects without bleaching
   - No harsh chemical smell
   - Odorless
   - Disinfects household surfaces
   - No Mixing Required
   - Kills *Staphylococcus aureus* in 30 seconds*
   - Kills *Salmonella choleraesuis* in 30 seconds*
   - Kills *Listeria monocytogenes* in 30 seconds*
   - Kills *Pseudomonas aeruginosa* in 30 seconds*
   - Kills germs in 30 seconds*

3. The following phrases from the 'Additional Language for Back Panel" have not been removed but have been revised as requested to remove the reference to 99.9999% where applicable:

- Kills *Staphylococcus aureus* in 30 seconds*
- Kills *Salmonella choleraesuis* in 30 seconds*
- Kills *Listeria monocytogenes* in 30 seconds*
- Kills *Pseudomonas aeruginosa* in 30 seconds*
- Kills germs in 30 seconds*

Thank you,
INNOVATIVE MEDICAL SERVICES

Michael L. Krall
President/CEO

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Certified Mail

December 17, 2003

Michael L. Krall
The consultant for
INNOVATIVE MEDICAL SERVICES
1725 Gillespie Way
El Cajon, California 92020

Subject: **AXEN® 30**
EPA Registration No. 72977-3

Dear Mr. Krall:

It was brought to my attention that the label stamped March 17, 2003 did not include the revisions as stated in the ***Registration Notice dated March 3, 2003*** (copy enclosed). Therefore, the label is **not** acceptable.

Within 30-days from the date of receipt of this certified letter, you must submit three (3) copies of the labeling bearing the revisions as stated in the Notice of Registration. Failure to comply with the conditions of the registration will result in cancellation of the subject product in accordance with FIFRA section 6(e).

Should you have any questions or comments concerning this letter, you may contact me at (703) 308-6422.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

cc: Laird Regulatory Consultants, Inc.

enclosure:

Please Read All Instructions Before Completing this Form *(Form must be typed)* Form Approved. OMB No. 2070-0044. Approval Expires 1-31-96

United States
Environmental Protection Agency
Office of Pesticide Programs (7505C)
Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product	Distributor Company Number
72977-3	81056

Note: Do not submit distributor product labels

Name of Registered Product *(basic product name accepted by EPA)*	Distributor Product Name
Xen 30	Clear Solutions

Name and Address of Distributor *(Type; include ZIP code)*

Earth Vitality Scents
219 W Cedar Ave., #7
Flagstaff, AZ 86001

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...","distributed by..."; or "sold by..." to show that the name is not that of the manufacturer
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor: Debra L Shannon

Date: 3-19-04

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant: PRESIDENT / CEO

Date: 03/19/04

EPA Form 8570-5 (Rev. 8-94) Previous editions are obsolete. White - EPA

URGENT

TASK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

A	Completed by Product Manager		
PRODUCT REVIEWER: Renee Whitaker			RMB II TEAM 34
Description of Action:			EPA File Symbol/Reg No.: 72977-3
Decision No. 340359	Submission No. 756067		Fee for Service Action Code:
FQPA Action Code: 332	Non-FQPA Action Code:		Fee for Service Fee: $
	MONTH	DAY	YEAR
APPLICATION DATE	03	10	2004
EPA PIN DATE	03	12	2004
REVIEWER ASSIGNED DATE	03	12	2004
[redacted] DATE DUE TO PM	03	16	2004
DATE DUE OUT OF AGENCY	03	18	2004

Type of Data:	Product Chemistry ☐	Acute Toxicology ☐	Efficacy ☐	Environmental Fate ☐	Ecological Effects ☐	Chronic Toxicology ☐	Exposure ☐

COMMENTS:

Renee: After consideration of the Agency's lack of policy on hard-non porous surfaces, we will accept this notification from [redacted] URGENT

DP Barcode No(s):

B	For Arctic Slope Contract Only		
Contractor: Arctic Slope		Contract No.:	TOPO/Alt. TOPO:
Draft Task: Signature _____ _____ (Est. hrs)		Final Task: Signature _____ _____ (Total hrs)	

C	Reviewer's Comments:

Response Code: 17	Response Date: 3-17-04

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 17, 2004

Elizabeth A. Brown, Ph.D.
Consultant
ChemReg International, LLC
Agent for ETI H2O
1990 Old Bridge Road, Suite 201
Lake Ridge, VA 22192

Subject: **Axen® 30**
EPA Registration Number 72977-3
Application dated March 10, 2004

Dear Dr. Brown:

This will acknowledge receipt of your notification, submitted under the provisions of PR Notice 98-10, FIFRA section 3 (c) 9.

Proposed Notification:

- add optional marketing statements

General Comment:

Based on a review of the material submitted, the following comment apply.

A copy of the notification has been inserted in your file for future reference.

Should you have any questions concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,

Renae F. Whitaker

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

Please read instructions on reverse before completing form

Form Approved, OMB No. 2070-0060, Approval expires 5-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
72977-3	Adam Heyward	[X] None [ ] Restricted
4. Company/Product (Name)	PM #	
Axen 30	33	
5. Name and Address of Applicant (include ZIP Code)	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:	
ETI H2O 1725 Gillespie Way El Cajon CA 92020	EPA Reg No. _____	
[ ] *Check if this is a new address*	Product Name _____	

Section - II

[ ] Amendment – Explain below
[ ] Resubmission in response to Agency letter dated _____
[X] Notification – Explain below
[ ] Final printed labels in response to Agency letter dated
[ ] "Me Too" Application
[ ] Other – Explain below

NOTIFICATION
Date Reviewed: 3-12-04
Reviewed By: [illegible]

Explanation. Use additional page(s) if necessary. (For Section I and Section II)
Notification of Other Labeling Revisions per PR Notice 98-10.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section III

1. Material This Product Will be Packaged in:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
[ ] Yes [X] No	[ ] Yes [X] No		[ ] Yes [X] No		[ ] Metal [X] Plastic [ ] Glass
***Certification must be submitted**	If "Yes" Unit Packaging wgt	No. per container	If "Yes" Package wgt	No. per container	[ ] Paper [ ] Other (Specify) _____

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of label directions
[X] Label [ ] Container	4-32 oz; 1-220 gallon	[X] On Label [ ] On Label accompanying product

Manner in Which Label is Affixed to Product: [X] Lithograph [X] Paper glued [ ] Stenciled [ ] Other _____

Section IV

1. Contact Person (*Complete items directly below for identification of individual to be contacted, if necessary, to process this application.*)

Name	Title	Telephone No. (Include Area Code)
Elizabeth Anne Brown	Authorized Agent	703-492-7905

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law

6. Date Application Received

(Stamped)

RECEIVED 3-12-04

2. Signature	3. Title	
Elizabeth Anne Brown	Authorized Agent	
4. Typed Name	5. Date	
Elizabeth Anne Brown	March 10, 2004	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White – EPA File Copy (Original) Yellow – Applicant Copy

ChemReg
INTERNATIONAL, LLC

1990 OLD BRIDGE ROAD, SUITE 201
LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-7905
MAIN: 703-492-0445
Fax: 703-492-0668

E-MAIL: brown@chemreg.com
WEB SITES: www.chemreg.com
www.pesticide.net

ELIZABETH A. BROWN, PH.D.

Hand Delivery

March 10, 2004

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

NOTIFICATION
Date Reviewed: 3-12-04
Reviewed By:

Attention: Adam Heyward (PM 34)

Re: Axen 30, EPA Reg. No. 72977-3
Notification of other labeling revisions per PR Notice 98-10

Dear Adam:

On behalf of our client, ETI H2O, we are notifying for optional marketing statements for "Axen 30." This submission is in full compliance with the notification procedure as identified in PR Notice 98-10. This is a resubmission of the notification originally submitted on December 3, 2003, in accordance with our phone call of March 9, 2004. During that phone call, you requested that this notification be resubmitted and identified that you would expedite acceptance based on your further consideration.

As required by PR Notice 98-10 for notifications for other labeling revisions, enclosed please find the following:

1. Application Form (8570-1), including the PR Notice 98-10 Certification Statement
2. One copy of the product labeling with each of the changes highlighted.

Please let me know if you have any questions about the enclosed items. Please either fax me a copy of the Agency's acceptance of this notification or contact me to pick up a stamped, accepted copy.

Regards,

Elizabeth Anne Brown

cc: ETI H2O

DISCLAIMER
3-12-04

Axen® 30

Disinfectant, Fungicide & Virucide*

NOTIFICATION
Date Reviewed: 3-12-04
Reviewed By:

NOTIFICATION
Date Reviewed: 3-12-04
Reviewed By:

(Disinfects and Deodorizes)
(Restaurants) • (Hospitals) • (Schools) • (Homes) •
(Offices)

Manufactured by ETI H2O
A Division of Innovative Medical
Services
1725 Gillespie Way
El Cajon, CA 92020
EPA REG. No. 72977-3
EPA EST. No. 72977-CA-001
Net Vol. 32 oz.

Active Ingredient	
Silver[1]	0.003%
Citric Acid	4.840%
Other Ingredients	95.157%
Total	100.000%

[1] Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

CAUTION

DISCLOSURE
3-12-04

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is a colorless, odorless broad spectrum antimicrobial disinfectant and deodorizer. Proven to kill bacteria, fungus and viruses*, **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** should be used on non-porous environmental hard surfaces in (homes), (hospitals), (nursing) (homes), (medical and dental clinics), (laboratories), (ambulance and patient transfer vehicles), (funeral homes), (hotels), (restaurants), (schools), (day care facilities), (offices), (veterinary clinics), (animal shelters), (kennels), (exercise facilities), (beauty and barber shops), (subways), (trains), (airplanes), (ships), (busses) and (other public transportation vehicles), (locker rooms), (kitchens) and (restrooms).

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray has been formulated to disinfect hard, non-porous environmental surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain) and objects including (walls), (floors), (counters), (sinks), (toilets), (cabinets), (tubs), (showers), (doorknobs), (lights switch covers), (telephones), (appliances), (stove tops), (bed frames), (wheelchairs), (over-bed tables), (examination tables) and (waste containers), (tables), and (chairs).

(This product) can be used in can be used in (homes), (schools), (nurseries), (daycare centers), (playrooms), (playground and/or recreational facilities), (washrooms), (kitchens), (restrooms and/or bathrooms), (school buses).

Use to disinfect the following hard, non-porous surfaces: (children's toys), (toys) (toy box(s)), (diaper pail(s)), (diaper changing table(s)), (bathroom and/or kitchen counter(s)), (desk(s)), (play table(s)), (computer keyboard), (telephone) (doorknob(s)), (jungle gym(s)), (playhouse(s)), (child car seat), (stroller(s)) (crib(s)), (playpen(s)), (activity center(s)), (tanning beds).

FAST, EASY, EFFECTIVE
General Information

***AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** successfully killed the following organisms under AOAC protocols (In order to ensure that all organisms listed are killed, you must use the contact times as directed in the Application Instructions):

Organism	Kill Time
Pseudomonas aeruginosa [1]	30 seconds
Staphylococcus aureus [1]	30 seconds
Salmonella choleraesuis [1]	30 seconds
Listeria monocytogenes [1]	30 seconds
Vancomycin resistant *Enterococcus faecium* [1]	2 minutes
Methicillin resistant *Staphylococcus aureus* [1]	2 minutes
Escherichia coli 0157:H7 [1]	2 minutes
Trichophyton mentagrophytes (Athlete's Foot Fungus)	10 minutes
HIV type 1- Strain HTLV IIIB [1]	30 seconds
Herpes Simplex Type 1 VR-733 F(1) Strain [2]	1 minute
Influenza A VR-544, Hong Kong strain [2]	10 minutes
Rhinovirus R37 VR-1147, Strain 151-1 [2]	10 minutes
Polio Type 2, VR-1002, Lansing Strain [2]	10 minutes

1 Evaluated in the presence of 5% organic soil.
2 Evaluated in the presence of 1% organic soil

NOTE: Bracketed information is optional wording for product specific labels

Fungicidal Activity: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is effective against *Trichophyton mentagrophytes*, the Athlete's foot fungus. Use in locker rooms, dressing rooms, shower and bath areas, and exercise facilities.

Deodorizes: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray reduces annoying odors caused by bacteria. Use to control odors in hospitals, nursing homes, public restrooms, animal kennels and barn stalls. In private homes, use in the kitchen, bathroom, sink rooms and basements.

APPLICATION INSTRUCTIONS

Surfaces that are heavy soiled with organic matter must be pre-cleaned prior to using this product.

General Disinfection:
For general disinfection and control of the bacteria *Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella choleraesuis, Listeria monocytogenes*, Vancomycin Resistant *Enterococcus faecium* (VRE), Methicillin Resistant *Staphylococcus aureus* (MRSA) and *Escherichia coli* 0157:H7 the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 2 minutes. The surface may then be wiped dry with a clean towel. When used as directed, **AXEN® 30™ Disinfectant, Fungicidal & Virucidal Spray** provides protection from *Pseudomonas aeruginosa, Staphylococcus aureus* and *Salmonella choleraesuis* up to 24 hours after initial application.

Fungus Control:
For effective control of the fungus *Trichophyton mentagrophytes*, the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel. Re-apply when cleaning or when new growth appears.

Viral Control:
To kill Herpes Simplex Type 1 F(1) Strain Influenza A Virus, Hong Kong strain, Rhinovirus R37 Strain 151-1, Polio Virus Type 2 Lansing Strain the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel

Kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV): **Instructions for Cleaning and Decontamination Against HIV** on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids: **Personal Protection**: When handling items soiled with blood or body fluids, use appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure**: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time**: Apply **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** to area to be treated. The surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 30 seconds. The surface may then be wiped dry with a clean towel. **Disposal of Infectious Materials:** Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

KEY: The following language will be printed on the label of products intended to be sold to health facilities:

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the human body, either into or in contact with the bloodstream, or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not normally penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

STORAGE AND DISPOSAL	
Storage:	Do not contaminate water, food or feed by storage or disposal.
Disposal:	Do not reuse container. Rinse thoroughly before discarding in trash or recycling.

IN CASE OF EMERGENCY
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact CHEMTREC 1-800-424-9300 for emergency medical treatment information.

Additional language for front panel

Kills *Staphylococcus aureus* in 30 seconds*
Kills *Salmonella choleraesuis* in 30 seconds*
Kills *Listeria monocytogenes* in 30 seconds*
Kills *Pseudomonas aeruginosa* in 30 seconds*
Kills germs in 30 seconds*
Kills common household germs
Kills common household germs including *Salmonella, Staphylococcus, Listeria,* and *E. coli.*
Kills *Salmonella, Staphylococcus, Listeria,* and *E. coli.*
Kills - Bacteria, Fungus and Virus*
No dulling residue
Disinfects without bleaching
No harsh chemical smell
Odorless
Disinfects household surfaces
No Mixing Required

KEY: *= Refer to table

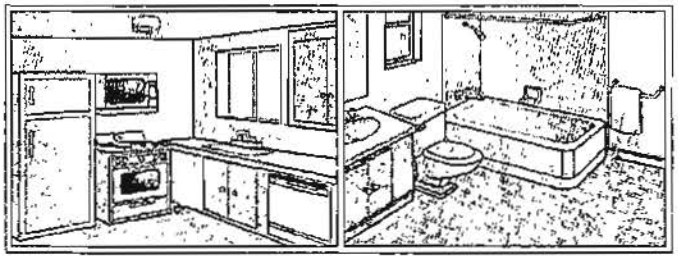
Alternate language for the back panel

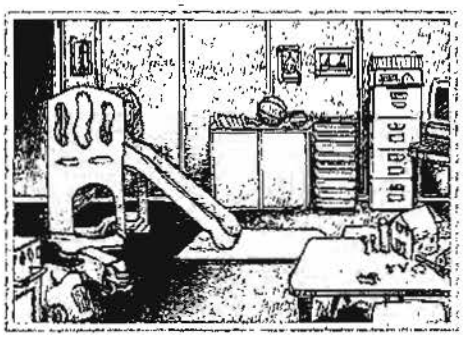
Kills *Staphylococcus aureus* in 30 seconds*
Kills *Salmonella choleraesuis* in 30 seconds*
Kills *Listeria monocytogenes* in 30 seconds*
Kills *Pseudomonas aeruginosa* in 30 seconds*
Kills germs in 30 seconds*

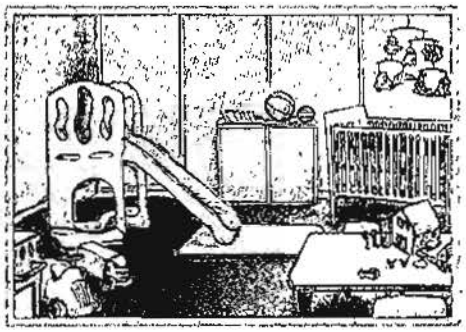
KEY: *= Refer to table

Alternate language for the front or back panel
Hospitality Environment
Institutional
Childcare Environments
Medical & Nursing Environment

Optional graphics for back of label (graphics are larger here than they will appear on the label)







Elizabeth Brown
<brown@chemreg.com
>

To: Adam Heyward/DC/USEPA/US@EPA
cc: "Blount Dolana (E-mail)" <dblount@imspure.com>
Subject: discussions on 72977-3

03/02/2004 09:22 AM

Adam:
As requested during our phone call this morning, the following are the background items and issues on this registrations that we will discuss on Thursday, March 4 (I will call you about 7:15 am). I hope we will be able to clarify any outstanding concerns at that time. This is a bit long, but I wanted to be sure we have all the same pieces and are talking about the same things.

Background:

- On March 3, 2003, the Agency issued the initial registration for this product, with a requirement for multiple label revisions.
- On March 10, 2003, the registrant submitted the required revised printed labels, based on the Agency's March 3 notice of registration and telephone conversations with you on March 6 and March 10. The agreements reached during the telephone conversations were outlined in the registrants letter with that resubmission.
- On March 17, 2003, the Agency approved the revised labeling without requirement for any further revisions or modifications. (We note that the March 17, 2003 stamped accepted label image does not appear on EPA's website with the March 3, 2003 label).
- On December 3, 2003, a notification consistent with PR 98-10 was submitted to add optional marketing statements for the registered uses as a disinfectant for hard, nonporous surfaces. (The cover letter and EPA pin-punch receipt date are December 3, 2003; the date on the application form (EPA Form 8570-1) is November 25, 2003).
- On December 17, 2003, the Agency sent a letter to the registrant stating that the label stamped March 17, 2003 did not include the revisions as stated in the March 3 notice of registration. (Note that this letter does not acknowledge the March 6 and 10 agreements reached with the Agency nor does it mention the December 3, 2003 notification submission).
- On January 15, 2004, after the registrant spoke with you about the December 17, 2003 letter (received by the registrant on January 5, 2004), they submitted revised labeling to the March 17, 2003 stamped accepted label to make an additional minor modification, reiterating the March 6 and 10, 2003 agreements. (Note that the label submitted on January 15, 2004 did not include the optional marketing statements submitted under notification on December 3, 2003).
- On February 25, 2004, the Agency sent a letter stating that the "amendment" dated November 25, 2003 was not acceptable, requiring response to the Agency letter of December 17, 2003 and stating that additional claims could not be added, with general comments about uses that needed to be revised. (This refers to the notification that was submitted on Dec 3, 2003 although the application form was dated November 25, 2003).

The areas I would like to discuss with you and to obtain clarification from the Agency are as follows:

- The Agency approved the label for Axen 30 on March 17, 2003, based on revisions made in agreement with the Agency. Yet the Agency's letter of December 17, 2003 states that the revisions required in the Notice of Registration were not made, seemingly ignoring the agreements reach with the Agency on March 6 and 10, 2003 and documented in the resubmission on March 10, 2003. Could you please clarify what concerns the Agency has or confirm that the label submitted Jan 15, 2004, revised in accordance with the Agency's written and verbal direction, is acceptable (with clarification for notification, following)?
- According to PR 98-10 (Section IV(A)(2)), the Agency must inform the registrant within 30 days of submission of a notification if the notification is disapproved and state the reasons why. The registrant can sell or distribute the product bearing the changes made under notification 60 days after submission if the Agency has not disapproved the modification by that time (specific approval is not required). The notification for this product was submitted on December 3, 2003; the 30 day period for EPA to disapprove the notification was January 2, 2003, and the 60 day period expired on February 1, 2003.

  The registrant did not at any time receive anything from the Agency disapproving the notification. Thus, the submitted notification is considered acceptable under Agency policy and procedure. However, the February 25, 2003 letter from the Agency (outside of both the 30 day and 60 day required timeframes) denies the submission, apparently considering it to be an amendment rather than notification.

  - Can you please address whether the notification is effective in light of the Agency's policy regarding timings?
  - Regarding the Agency's letter of February 25, 2004: The Agency has provided its internal guidance to industry that confirms all hard, nonporous surfaces for disinfectants are covered by registration for hard, nonporous surfaces assuming the use sites are covered (Internal guidance for the review process for registration and use directions for floor wipe towelette products, 10/16/03 - "floors do not represent a new use site for labels which already specify treatment on hard, non-porous surfaces"). While this guidance is for towelettes, it is consistent with the Agency's many prior decisions for disinfectants used on hard, non-porous surfaces - specific items do not need to be added as new use sites within the use site categories; the specific items do not need to be identified but can be listed as optional marketing statements within the categories (eg., see 777-89).

    Axen 30 is registered as a disinfectant for hard, non-porous surfaces in " homes, hospitals, nursing homes, medical and dental clinics, laboratories... schools, day care facilities...kitchens..." (emphasis added). Given that,

could you please explain the concerns expressed in the Agency letter of February 25, 2004? All of the optional marketing statements are for common hard, non-porous surfaces within those use sites and are commonly listed as optional marketing statements on other disinfectants for hard, non-porous surfaces. These have not previously been considered to be additional claims or new use sites.

I would like to ensure that the registrant understands the Agency's concerns, policies (and any changes from past policy which are being implemented with the more recent actions), and then make certain that the registration for this product is revised/corrected as needed or that the label as it currently stands is determined to be acceptable. I'm concerned that there has been some miscommunication or perhaps that communications have crossed each other without being fully addressed.

Thanks very much for your help on this. I'll look forward to talking with you on Thursday morning to get this figured out.

Elizabeth

Elizabeth Anne Brown, Ph.D.
Director, Scientific & Regulatory Affairs
ChemReg International
1990 Old Bridge Road, Suite 201
Lake Ridge, VA 22192

Phone: 703-492-7905
Fax: 703-492-0668
Email: brown@chemreg.com

PM WORK ASSIGNMENT SHEET

DECISION 328293 **PM** 34

DESCRIPTION OF ACTION:

SUBMISSION BAR CODE: S 753125

PRODUCT REVIEWER: ~~SG Eng~~ R. Whitaker

FILE SYMBOL/REG NO.: 70644-3

FQPA ACTION CODE: 302 NON-FQPA ACTION CODE:

AMOUNT OF TIME TO COMPLETE TASK (ASRC only)	HOURS

	MONTH	DAY	YEAR
APPLICATION DATE	01	15	04
EPA PIN DATE	01	20	04
REVIEWER ASSIGNED DATE	01	21	04
DATE DUE OUT OF AGENCY	02	27	04

TYPE OF DATA

Product Chemistry: ☐ **Product Toxicology:** ☐ **Efficacy:** ☐

RASSB: ☐ **HED TOX** ☐ **ENVIRONMENTAL FATE** ☐ **FISH/WILDLIFE** ☐

Other ☐

COMMENTS:

JACKET(S)/FILE SHOULD BE SUBMITTED WITH YOUR LETTERS FOR SIGNATURE

RESPONSE CODE: 2 RESPONSE DATE: 2 / 25 / 04
MO Day Year

PM WORK ASSIGNMENT SHEET

DECISION 336362 **PM** 34

DESCRIPTION OF ACTION: _____

SUBMISSION BAR CODE: S 750550

PRODUCT REVIEWER: Deanna Wilson

FILE SYMBOL/REG NO.: 71971-2

FQPA ACTION CODE: 302 **NON-FQPA ACTION CODE:** _____

AMOUNT OF TIME TO COMPLETE TASK (ASRC only)	HOURS_____

	MONTH	DAY	YEAR
APPLICATION DATE	12	03	03
EPA PIN DATE	12	04	03
REVIEWER ASSIGNED DATE	12	05	03
DATE DUE OUT OF AGENCY	01	09	04

TYPE OF DATA

Product Chemistry: ☐ **Product Toxicology:** ☐ **Efficacy:** ☐

RASSB: ☐ **HED TOX** ☐ **ENVIRONMENTAL FATE** ☐ **FISH/WILDLIFE** ☐

Other ☐ _____

COMMENTS:

_____

_____

_____

_____

_____

_____

_____

JACKET(S)/FILE SHOULD BE SUBMITTED WITH YOUR LETTERS FOR SIGNATURE

RESPONSE CODE: _____ RESPONSE DATE: ____/____/____
MO Day Year

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

February 25, 2004

Elizabeth A. Brown, Ph.D.
Consultant
ChemReg International, LLC
Agent for ETI H2O
1990 Old Bridge Road, Suite 201
Lake Ridge, VA 22192

Dear Dr. Brown:

Subject: **Axen® 30**
EPA Registration No. 72977-3
Application Dated November 25, 2003

The following amendments submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, are not acceptable for the following reasons:

Proposed Amendments:

- Response to Agency Letter dated December 17, 2003
- Adding additional claims to label

General Comments:

1. You must delete the claims children's toys, toy box, diaper pails, diaper changing table, kitchen counter, play tables, jungle gym, playhouse, child car seat, strollers, playpens and activity centers.

2. You must specify cite(s) within the various facilities. You must also specify the material of the cabinets.

3. Remove pictures of playroom from the label.

	CONCURRENCES							
SYMBOL								
SURNAME								
DATE								

Other Comments:

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,

Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

EPA

01·20·04

January 15, 2004

Adam Heyward, PM 34
US EPA
Office of Pesticide Programs
Regulatory Branch II
Antimicrobials Division (7510C)
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

SUBJECT: Axen30
EPA Product Registration Number 72977-3
Reply to December 17, 2003 letter, received January 5, 2004

Dear Mr. Heyward:

I am in receipt of your letter dated December 17, 2003 which claims that we did not amend our product label as detailed in your March 3, 2003 letter.

As you will recall, I spoke with you on March 6 and March 10 to discuss certain items contained in your March 3, 2003 letter. Together, we agreed to certain modifications of the items to be amended and I submitted to you a letter summarizing our conversation and detailing our understanding of the changes to be made, along with 3 copies of the final amended label. Subsequently, we received a stamped approved label dated March 17, 2003. A copy of our reply letter is attached for your reference.

Upon re-reviewing the March 3 label and our reply, I do see that we neglected only to eliminated the phrase "such as" from two locations (ref. Item 2(i)). Attached is the revised label deleting this phrase wherever it appeared. I apologize for the confusion and thank you for bringing it to our attention.

Should you have an further concerns, please do not hesitate to contact me.

Best Regards,
INNOVATIVE MEDICAL SERVICES

Michael Krall
President/CEO

EPA

01·20·04

March 10, 2003

COPYATIVE

INNOVATIVE MEDICAL SERVICES

a NASDAQ company

Adam Heyward, PM 34
US Environmental Protection Agency
Office of Pesticide Programs
Regulatory Management Branch II
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

SUBJECT Axen30
EPA product Reg. Number 72977-3
Telecom of March 6, and 10, 2003

Dear Mr. Heyward:

Attached are three (3) copies of the revised final printed label bearing the revisions outlined in the March 3, 2003 Registration Notice with the exception of the following modifications as verbally approved by you in our telephone conferences referenced above:

1. The chart will remain as originally submitted and the statement below will be added directly above the chart:
   "In order to ensure that all organisms listed are killed, you must use the contact times as directed in the Application Instructions"

2. The following phrases from the 'Additional Language for Front Panel" have not been removed but have been revised as requested to remove the reference to 99.9999% where applicable:
   - No dulling residue
   - Disinfects without bleaching
   - No harsh chemical smell
   - Odorless
   - Disinfects household surfaces
   - No Mixing Required
   - Kills *Staphylococcus aureus* in 30 seconds*
   - Kills *Salmonella choleraesuis* in 30 seconds*
   - Kills *Listeria monocytogenes* in 30 seconds*
   - Kills *Pseudomonas aeruginosa* in 30 seconds*
   - Kills germs in 30 seconds*

3. The following phrases from the 'Additional Language for Back Panel" have not been removed but have been revised as requested to remove the reference to 99.9999% where applicable:

EPA

- Kills *Staphylococcus aureus* in 30 seconds*
- Kills *Salmonella choleraesuis* in 30 seconds*
- Kills *Listeria monocytogenes* in 30 seconds*
- Kills *Pseudomonas aeruginosa* in 30 seconds*
- Kills germs in 30 seconds*

Thank you,
INNOVATIVE MEDICAL SERVICES

Michael L. Krall
President/CEO

ChemReg
INTERNATIONAL, LLC

1990 OLD BRIDGE ROAD, SUITE 201
LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-7905
MAIN: 703-492-0445
Fax: 703-492-0668

E-MAIL: brown@chemreg.com
WEB SITES: www.chemreg.com
www.pesticide.net

ELIZABETH A. BROWN, PH.D.

December 3, 2003

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attention: Adam Heyward (PM 34)

Re: Axen 30, EPA Reg. No. 72977-3
Notification of other labeling revisions per PR Notice 98-10

Dear Adam:

On behalf of our client, ETI H2O, we are notifying for optional marketing statements for "Axen 30." This submission is in full compliance with the notification procedure as identified in PR Notice 98-10.

As required by PR Notice 98-10 for notifications for other labeling revisions, enclosed please find the following:

1. Application Form (8570-1), including the PR Notice 98-10 Certification Statement
2. One copy of the product labeling with each of the changes highlighted.

Also enclosed is a copy of the letter of authorization for ChemReg International, LLC, to act on behalf of ETI H2O. Please let me know if you have any questions about the enclosed items.

Regards,

Elizabeth Anne Brown

Elizabeth Anne Brown

cc: ETI H2O

November 21, 2003

Document Processing Dest (COADR)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attn: Mr. Jim Jones, OPP Director

Re: Authorized Company Representative

Dear Mr. Jones:

This letter authorizes the staff of ChemReg International, LLC, at 1990 Old Bridge Road, Suite 201, Lake Ridge, VA 22192, to act as our agents in all regulatory matters relative to our products, and they can access information from your files. I shall remain as the principal company contact at the address stated above.

This authorization supersedes all previous letters on the subject and shall remain in effect until such time as ETI H2O notifies EPA, in writing, of a change.

If you have any questions, please call.

Sincerely,
ETI H2O

Michael L. Krall
President/CEO

cc: E. Brown, ChemReg International (703-492-7905; brown@chemreg.com)
F. Sanders, US EPA/OPP/AD
M. Swindell, US EPA/OPP/AD
A. Heyward, US EPA/OPP/AD

1725 Gillespie Way • El Cajon, CA 92020 • telephone 619-596-8600 • facsimile 619-596-8700

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [ ] Amendment
- [x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
72977-3	Adam Heyward	[x] None [ ] Restricted
4. Company/Product (Name)	PM# 34	
Axen 30		

5. Name and Address of Applicant *(Include ZIP Code)*

ETI H2O
1725 Gillespie Way
El Cajon CA 92020

[ ] *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [redacted] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [x] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of Other Labeling Revisions per PR Notice 98-10.
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
[redacted]*ertification must submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container	4-32 oz, 1-220 gallon	[ ]

6. Manner in Which Label is Affixed to Product: [x] Lithograph [x] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Elizabeth Brown, ChemReg International, LLC.		703-492-7505

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingllly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received
[signature]	Regulatory Director	[Stamped]
4. Typed Name: Dolana Blount	5. Date: 11-25-03	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

EPA

Axen® 30

Disinfectant, Fungicide & Virucide*

Disinfects and Deodorizes
Restaurants • Hospitals • Schools • Homes • Offices

Manufactured by ETI H2O
A Division of Innovative Medical Services
1725 Gillespie Way
El Cajon, CA 92020
EPA REG. No. 72977-3
EPA EST. No. 72977-CA-001
Net Vol. 32 oz.

Active Ingredient	
Silver[1]	0.003%
Citric Acid	4.840%
Other Ingredients	95.157%
Total	100.000%

[1] Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is a colorless, odorless broad spectrum antimicrobial disinfectant and deodorizer. Proven to kill bacteria, fungus and viruses*, AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray should be used on non-porous environmental hard surfaces in homes, hospitals, nursing homes, medical and dental clinics, laboratories, ambulance and patient transfer vehicles, funeral homes, hotels, restaurants, schools, day care facilities, offices, veterinary clinics, animal shelters, kennels, exercise facilities, beauty and barber shops, subways, trains, airplanes, ships, busses and other public transportation vehicles, locker rooms, kitchens and restrooms.

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray has been formulated to disinfect hard, non-porous environmental surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain) and objects including walls, floors, counters, sinks, toilets, cabinets, tubs, showers, doorknobs, lights switch covers, telephones, appliances, stove tops, bed frames, wheelchairs, over-bed tables, examination tables and waste containers, tables, and chairs.

FAST, EASY, EFFECTIVE
General Information

*AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray successfully killed the following organisms under AOAC protocols (In order to ensure that all organisms listed are killed, you must use the contact times as directed in the Application Instructions):

Organism	Kill Time
Pseudomonas aeruginosa [1]	30 seconds
Staphylococcus aureus [1]	30 seconds
Salmonella choleraesuis [1]	30 seconds
Listeria monocytogenes [1]	30 seconds
Vancomycin resistant *Enterococcus faecium* [1]	2 minutes
Methicillin resistant *Staphylococcus aureus* [1]	2 minutes
Escherichia coli 0157:H7 [1]	2 minutes
Trichophyton mentagrophytes (Athlete's Foot Fungus)	10 minutes
HIV type 1- Strain HTLV IIIB [1]	30 seconds
Herpes Simplex Type 1 VR-733 F(1) Strain [2]	1 minute
Influenza A VR-544, Hong Kong strain [2]	10 minutes
Rhinovirus R37 VR-1147, Strain 151-1 [2]	10 minutes
Polio Type 2, VR-1002, Lansing Strain [2]	10 minutes

1 Evaluated in the presence of 5% organic soil.
2 Evaluated in the presence of 1% organic soil

Fungicidal Activity: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is effective against *Trichophyton mentagrophytes*, the Athlete's foot fungus, Use in locker rooms, dressing rooms, shower and bath areas, and exercise facilities.

Deodorizes: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray reduces annoying odors caused by bacteria. Use to control odors in hospitals, nursing homes, public restrooms, animal kennels and barn stalls. In private homes, use in the kitchen, bathroom, sink rooms and basements.

APPLICATION INSTRUCTIONS

Surfaces that are heavy soiled with organic matter must be pre-cleaned prior to using this product.

General Disinfection:

For general disinfection and control of the bacteria *Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella choleraesuis, Listeria monocytogenes,* Vancomycin Resistant *Enterococcus faecium* (VRE), Methicillin Resistant *Staphylococcus aureus* (MRSA), and *Escherichia coli* O157:H7 the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 2 minutes. The surface may then be wiped dry with a clean towel. When used as directed, **AXEN® 30™ Disinfectant, Fungicidal & Virucidal Spray** provides protection from *Pseudomonas aeruginosa, Staphylococcus aureus* and *Salmonella choleraesuis* up to 24 hours after initial application.

Fungus Control:
For effective control of the fungus *Trichophyton mentagrophytes*, the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel. Re-apply when cleaning or when new growth appears.

Viral Control:
To kill Herpes Simplex Type 1 F(1) Strain Influenza A Virus, Hong Kong strain, Rhinovirus R37 Strain 151-1, Polio Virus Type 2 Lansing Strain the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel

Kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV): Instructions for Cleaning and Decontamination Against HIV on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids: **Personal Protection:** When handling items soiled with blood or body fluids, use appropriate barrier protection including latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** Apply **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** to area to be treated. The surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 30 seconds. The surface may then be wiped dry with a clean towel. **Disposal of Infectious Materials:** Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

KEY: The following language will be printed on the label of products intended to be sold to health facilities:

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the human body, either into or in contact with the bloodstream, or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not normally penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

STORAGE AND DISPOSAL	
Storage:	Do not contaminate water, food or feed by storage or disposal.
Disposal:	Do not reuse container. Rinse thoroughly before discarding in trash or recycling.

IN CASE OF EMERGENCY
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact CHEMTREC 1-800-424-9300 for emergency medical treatment information.

EPA

Additional language for front panel

Kills *Staphylococcus aureus* in 30 seconds*
Kills *Salmonella choleraesuis* in 30 seconds*
Kills *Listeria monocytogenes* in 30 seconds*
Kills *Pseudomonas aeruginosa* in 30 seconds*
Kills germs in 30 seconds*
Kills common household germs
Kills common household germs including *Salmonella, Staphylococcus, Listeria*, and *E. coli.*
Kills *Salmonella, Staphylococcus, Listeria*, and *E. coli.*
Kills - Bacteria, Fungus and Virus*
No dulling residue
Disinfects without bleaching
No harsh chemical smell
Odorless
Disinfects household surfaces
No Mixing Required

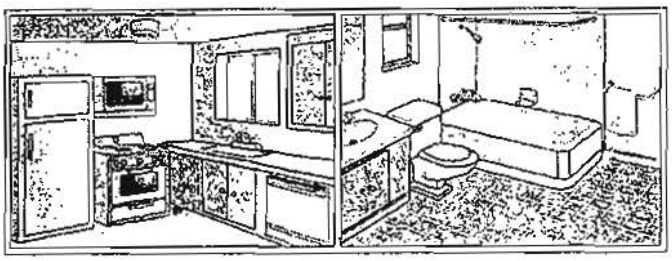
KEY: * = Refer to table

Alternate language for the back panel

Kills *Staphylococcus aureus* in 30 seconds*
Kills *Salmonella choleraesuis* in 30 seconds*
Kills *Listeria monocytogenes* in 30 seconds*
Kills *Pseudomonas aeruginosa* in 30 seconds*
Kills germs in 30 seconds*

KEY: * = Refer to table

Optional graphics for back of label (graphics are larger here than they will appear on the label)



KITCHEN BATHROOM

PM WORK ASSIGNMENT SHEET

DECISION 33,559 PM 34

DESCRIPTION OF ACTION: _____

SUBMISSION BAR CODE: S 250821

PRODUCT REVIEWER: Gray

FILE SYMBOL/REG NO.: 72917-3

FQPA ACTION CODE: 422 NON-FQPA ACTION CODE: _____

AMOUNT OF TIME TO COMPLETE TASK (**ASRC** only)	HOURS _____

	MONTH	DAY	YEAR
APPLICATION DATE	11	26	03
EPA PIN DATE	11	26	03
REVIEWER ASSIGNED DATE	12	15	03
DATE DUE OUT OF AGENCY	12	23	03

TYPE OF DATA

Product Chemistry: ☐ **Product Toxicology:** ☐ **Efficacy:** ☐

RASSB: ☐ **HED TOX** ☐ **ENVIRONMENTAL FATE** ☐ **FISH/WILDLIFE** ☐

Other ☐ _____

COMMENTS:

_____

_____

_____

_____

_____

_____

_____

JACKET(S)/FILE SHOULD BE SUBMITTED WITH YOUR LETTERS FOR SIGNATURE

RESPONSE CODE: 17 RESPONSE DATE: 12 / 22 03
MO Day Year

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 22, 2003

Dolana Blount
Regulatory Director
ETI H2O
Division of Innovative Medical Services
1725 Gillespie Way
El Cajon, CA 92020

Subject: **Axen 30**
EPA Registration No. 72977-3
Application Date: November 26, 2003
EPA Received Date: November 28, 2003

Dear Ms. Blount:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

- Alternate Brand Name ***"Kinderguard"***

General Comments

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510 C)

"Michael L. Krall"
<mkrall@imspure.com
>

03/04/2003 10:27 PM

To: Adam Heyward/DC/USEPA/US@EPA
cc: Dolana Blount <dblount@imspure.com>, laird1olivia@aol.com, jmoore10@cox.net, Gene Auerbach <gauerbach@imspure.com>, imspres@aol.com
Subject: Innovative Medical Services: Registration Notice for 72977-3

<?xml:namespace prefix = st1 ns = "urn:schemas-microsoft-com:office:smarttags" />March 4, 2003<?xml:namespace prefix = o ns = "urn:schemas-microsoft-com:office:office" />

Adam Heyward
US EPA
Product Manager (34)
Antimicrobials Division (7510C)

Ref: EPA Product Registration 72977-3, Dated March 3, 2003

Dear Mr. Heyward:

Thank you for your time this afternoon. As we discussed, outlined below are the specific points we would like you to address with your Microbiologist.

EPA Comment 2 b., Page 2 (March 3, 2003)– "On page 2, the chart which listed the kill time under the heading General Information for the bacteria Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella choleraesuis and Listeria monocytogenes ***must be changed from 30 seconds to Two Minutes in the chart and, wherever it appears on the label.":***

It appears the AOAC testing data submitted for Axen30 has been overlooked, in that you request that we alter the kill times listed in the chart under General Information for the bacteria *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis* and *Listeria monocytogenes* from 30 seconds to 2 minutes.

Although we disagreed, we complied with the request in your letter dated January 28, 2003, that we amend the label's USE INSTRUCTIONS to reflect that for disinfection, 'the surface must remain wet for 2 minutes'. Please refer to PAGE 13 of MRID 457572-03: AOAC Use Dilution – Carrier Confirmation (Lab ID 194972). The 30 ppm strength product was tested at 30 seconds following EPA testing and reporting guidelines, and **completely eliminated *Pseudomonas aeruginosa, Staphylococcus aureus* and *Salmonella choleraesuis* at the 30 second time point.**

Thus, the 30 second kill time is completely accurate for Pseudomonas aeruginosa, Staphylococcus aureus and Salmonella choleraesuis, while the 2 minute kill time is accurate for Methicillin Resistant S. aureus, Vancomycin Resistant Entercoccus and E. coli as reflected in MRID 457572-02.

Please also refer to PAGE 14 of MRID 457572-02 AOAC Use Dilution – Carrier Confirmation (Lab ID 197155) which confirms that Axen30 **completely eliminated *Listeria monocytogenes* in 30 seconds** following EPA testing and reporting guidelines.

We ask that the Agency allow the label chart to reflect the true and accurate test results as

outlined above including the allowance of the 30-second kill time against Pseudomonas *aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis* and *Listeria monocytogenes* and amend It's registration notice to reflect this allowance. In the Agency's label review dated January 28, 2003, we were advised to reference the table on page 2 of the label for qualification in regard to the specific organisms Axen30 is effective against and the associated kill times for each organism tested. We feel that the chart should remain as-is because it factually represents the test results and is the most straight-forward vehicle to inform the consumer.

Our intent is to help the consumer understand the difference between our Category IV disinfectant, which eliminates or kills *Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella choleraesuis and Listeria monocytogenes* in 30 seconds, and the more toxic Category II market leader, Lysol Brand II disinfectant, which claims on the front of their product label, "Kills 99.9% of germs in 30 seconds**" . The back of the Lysol product label reads "****Sanitizes**: Kills 99.9% of *Staphylococcus aureus* (*Staph*) and *Klebsiella pneumonia* (*K. pneumonia*) on hard non-porous surfaces in 30 seconds.". As you know, sanitization is simply a reduction in bacteria versus disinfection, a complete elimination of bacteria, as accomplished by Axen30 in 30 seconds when tested against *Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella choleraesuis and Listeria monocytogenes.* Lysol's Brand II disinfectant Product Registration number is 777-72.

EPA Comment 2 c, Page 2 – "The kill time for Herpes Simplex Type 1 VR-733 F(1) Strain ***must be changed from one minute to Ten Minutes in the chart and, wherever it appears on the label****".*

In your letter dated January 28, 2003, the agency acknowledges that MRID 457572-08 "*support the use of the product Axen®, at a dilution of 30 ppm, as a virucide when tested against Herpes simplex type 1, (VR-733) on hard, non-porous, inanimate surfaces with a 1% organic soil load with one and ten minute exposures at room temperature*". A review of pages 8, 12 and 13 of MRID 457572-08 will confirm these results.

We ask that the Agency allow the label to accurately reflect the efficacy of Axen30 at ***One Minute*** against Herpes simplex type 1 as tested following EPA testing and reporting guidelines and amend It's registration notice to reflect this change.

EPA Comment 2 d, Page 2 – "On the 4th page of the label, delete the statements "eliminates" or "Kills 99.99999 (sic), etc..." Only the following statements under the headings on page 4 of the label are acceptable:

Additional Language for Front Panel

- *Kill common household germs*
- *Kill common household germs, including Salmonella, Staphylococcus, Listeria and E.coli.*
- *Kills bacteria, Fungus and Virus**

Alternate Language for the Back Panel

- *None of the alternate language for the back panel is acceptable and therefore must be deleted from the label":*

Under the "Alternate language for the front of the label", you eliminated several phrases that were not previously rejected. We ask that you re-consider the following phrases as alternate wording in our final label as they do not relate to efficacy of the product and are merely descriptive informational phrases provided for the consumers benefit:

- No dulling residue
- Disinfects without bleaching
- No harsh chemical smell
- Odorless
- Disinfects household surfaces
- No mixing required

In addition, as Axen30 demonstrated efficacy in ***completely eliminating*** *Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella choleraesuis and Listeria monocytogenes* ***in 30 seconds*** following EPA testing and reporting guidelines , we ask that you re-consider the phrases below as alternate wording for the front or back panel of the label:

- Kills Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella choleraesuis, and Listeria monocytogenes in 30 seconds*
- Kills Staphylococcus aureus in 30 seconds*
- Kills Salmonella choleraesuis in 30 seconds*
- Kills Listeria monocytogenes in 30 seconds*
- Kills Pseudomonas aeruginosa in 30 seconds
- Kills 99.9999% of germs in 30 seconds*
- Kills germs in 30 seconds*
- Kills 99.9999% of Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella choleraesuis, and Listeria monocytogenes in 30 seconds*
- Kills 99.9999% of Staphylococcus aureus in 30 seconds*
- Kills 99.9999% of Salmonella choleraesuis in 30 seconds*
- Kills 99.9999% of Listeria monocytogenes in 30 seconds*
- Kills 99.9999% of Pseudomonas aeruginosa in 30 seconds*

KEY: * = Refer to table

As you suggested, we will call you in the morning at 10:30 am EST to touch base and offer you any clarification you may need at that time. I then suggest that we initiate a call to you at 3:00 pm EST, if that is convenient for you. This will allow you time to discuss our requests with your Microbiologist.
We are a small company on a critical time-line and therefore; we ask that this not be placed in another review period, as all the data has been sufficiently reviewed to address the matters at hand.

Adam, we appreciate your efforts in this matter and look forward to speaking with you tomorrow.

Respectfully,

Michael L. Krall, CEO

Innovative Medical Services

Ph. (619) 596-8600 Ext. 0

Fax (619) 596-8790

mkrall@imspure.com

SUBMISSION BAR CODE # 5629041 REVIEWER D. Copeland

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 72977-G PM 34 ACTION CODE 187

DESCRIPTOR Revised Labeling

[ ] CHILD RESISTANT PACKAGING [ ] CERTIFICATION
[ ] NON-RESIDENTIAL USE ONLY
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION	EPA RECEIVE DATE	PM RECEIVE DATE
2 5 03	2 5 03	2 7 03

~~METHOD OF SUPPORT~~

[ ] ~~CITE-ALL~~
[ ] ~~SELECTIVE~~
[ ] ~~NOT SUBMITTED~~
[ ] ~~NOT APPLICABLE~~
[ ] ~~INCORRECT/RESUB~~

~~FORMULATORS EXEMPTION~~

[ ] ~~SUBMITTED~~
[ ] ~~NOT SUBMITTED~~
[ ] ~~NOT APPLICABLE~~
[ ] ~~INCORRECT/RESUB~~

REVIEW(S) REQUESTED	DATA PACK #	~~DATE SENT~~	~~DUE DATE~~	~~DATE RETURNED~~
CHEMISTRY				
EFFICACY				
TOXICOLOGY				
HED TOX.				
ENVIRON. FATE				
FISH/WILDLIFE				
OTHER				

STATUS

RESPONSE CODE 15 RESPONSE DATE 3/3/03

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460-0001

NOTICE OF PESTICIDE:

X Registration
___ Reregistration

(Under FIFRA, as amended)

EPA Reg. Number	Date of Issuance
72977-3	March 3, 2003

Terms of Issuance: Conditional

Name of Pesticide Product: **AXEN® 30**

Name and Address of Registrant (include ZIP Code)

Innovative Medical Service
1725 Gillespie Way
El Cajon, California 92020

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above-named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

   a. Revise the EPA Registration Number to read " EPA Registration Number 72977-3"

Signature of Approving Official

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

Date: **March 3, 2003**

EPA Form 8570-6

b. On page 2, the chart which listed the kill time under the heading **General Information** for the bacteria "*Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella choleraesuis* and *Listeria monocytogenes* must be changed from 30 second to ***Two Minutes*** in the chart and, wherever it appears on the label."

c. The kill time for Herpes Simplex Type 1 VR-733 F(1) Strain must be changed from one minute to ***Ten Minutes*** in the chart and, wherever it appears on the label.

d. On the 4th page of the label, delete the statements "eliminates" or "Kills 99.99999, etc . . ." Only the following statements under the headings on page 4 of the label are acceptable:

Additional Language for Front Panel

- Kill common household germs
- Kill common household germs, including Salmonella, Staphylococcus, Listeria and E. coli.
- Kills Bacteria, Fungus and Virus*

Alternate Language for the Back Panel

- None of the alternate language for the back panel is acceptable and therefore must be deleted from the label

e. Delete the word ***"Eliminates"*** wherever it appears on the label and replaces it with the word "to kill or to control."

f. Delete the ingredient "Ionic Sliver" from the product name or add the ingredient "Citric Acid" to the product name.

g. The "Keep Out of Reach of Children" statement must be placed below the ingredient statement, along with the signal word **"Caution."**

h. Since no residual data was submitted to support the claim "*Do not clean treated surfaces after application if 24 hour protections are expected to be maintained,*" you must delete the claim wherever it appears on the label.

i. With respect to the statement concerning Athlete's foot fungus, delete the statement, "and any other hard, non-porous surfaces."

j. Since this product will be used in hospital and other health facilities, the following statement must be added to the label:

"This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the human body, either into or in contact with the bloodstream, or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not enter ordinarily penetrates the blood barrier or otherwise enter normal sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection."

Refer to PR Notice 94-4 for detailed information.

h. Delete the statement, "and other areas requiring control of microbial contamination" from the direction for use section. All intended cites must be specified on the label.

i. In the second paragraph on page 2, delete the word "such as" and other areas of the label where it appears.

Refer to the EPA letter dated January 28, 2003 for detailed information and/or unacceptable label statements.

3. Submit three (3) copies of the revised final printed label bearing the revisions prior to releasing this product for sale.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

Enclosure:

Stabilized Ionic Silver

Axen® 30

Disinfectant, Fungicide & Virucide*

Disinfects and Deodorizes
Restaurants • Hospitals • Schools • Homes • Offices

KEEP OUT OF REACH OF CHILDREN

(17)

Single word must be in place under the KOR OC

Active Ingredient	
Silver‡	0.003%
Citric Acid	4.840%
Other Ingredients	95.157%
Total	100.000%

‡ Electrolytically generated Silver ions

Manufactured by ETI H2O
A Division of Innovative Medical Services
1725 Gillespie Way
El Cajon, CA 92020

EPA REG. No. 72977-
EPA EST. No. 72977-CA-001

Net Vol. 32 oz.

Stabilized Ionic Silver

Axen® 30

Disinfectant, Fungicide & Virucide*

Disinfects and Deodorizes

Restaurants • Hospitals • Schools • Homes • Offices

ACCEPTED
with COMMENTS
- EPA Letter Dated:

MAR - 3 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 72977-3

KEEP OUT OF REACH OF CHILDREN

Active Ingredient	
Silver‡	0.003%
Citric Acid	4.840%
Other Ingredients	95.157%
Total	100.000%

‡ Electrolytically generated Silver ions

Manufactured by ETI H2O
A Division of Innovative Medical Services
1725 Gillespie Way
El Cajon, CA 92020

EPA REG. No. 72977-
EPA EST. No. 72977-CA-001

Net Vol. 32 oz.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is a colorless, odorless broad spectrum antimicrobial disinfectant and deodorizer. Proven to eliminate bacteria, fungus and viruses*, **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** should be used on non-porous environmental hard surfaces in homes, hospitals, nursing homes, medical and dental clinics, laboratories, ambulance and patient transfer vehicles, funeral homes, hotels, restaurants, schools, day care facilities, offices, veterinary clinics, animal shelters, kennels, exercise facilities, beauty and barber shops, subways, trains, airplanes, ships, busses and other public transportation vehicles, locker rooms, kitchens, restrooms and other areas requiring control of microbial contamination.

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray has been formulated to disinfect hard, non-porous environmental surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain) and objects such as walls, floors, counters, sinks, toilets, cabinets, tubs, showers, doorknobs, lights switch covers, telephones, appliances, stove tops, bed frames, wheelchairs, over-bed tables, examination tables and waste containers, tables, and chairs.

FAST, EASY, EFFECTIVE
General Information

* **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** demonstrated effective elimination of the following organisms under AOAC protocols:

Organism	Kill Time
Pseudomonas aeruginosa [1]	30 seconds
Staphylococcus aureus [1]	30 seconds
Salmonella choleraesuis [1]	30 seconds
Listeria monocytogenes [1]	30 seconds
Vancomycin resistant *Enterococcus faecium* [1]	2 minutes
Methicillin resistant *Staphylococcus aureus* [1]	2 minutes
Escherichia coli 0157:H7 [1]	2 minutes
Trichophyton mentagrophytes (Athlete's Foot Fungus)	10 minutes
HIV type 1- Strain HTLV IIIB [1]	30 seconds
Herpes Simplex Type 1 VR-733 F(1) Strain [2]	1 minute
Influenza A VR-544, Hong Kong strain [2]	10 minutes
Rhinovirus R37 VR-1147, Strain 151-1 [2]	10 minutes
Polio Type 2, VR-1002, Lansing Strain [2]	10 minutes

1 Evaluated in the presence of 5% organic soil.
2 Evaluated in the presence of 1% organic soil

Fungicidal Activity: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is effective against *Trichophyton mentagrophytes*, the Athlete's foot fungus. Use in locker rooms, dressing rooms, shower and bath areas, exercise facilities or any other hard, non-porous surface.

Deodorizes: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray reduces annoying odors caused by bacteria. Use to control odors in hospitals, nursing homes, public restrooms, animal kennels and barn stalls. In private homes, use in the kitchen, bathroom, sink rooms and basements.

APPLICATION INSTRUCTIONS

Surfaces that are heavy soiled with organic matter must be pre-cleaned prior to using this product.

General Disinfection:
For general disinfection and elimination of bacteria such as *Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella cholerasuis, Listeria monocytogenes,* Vancomycin Resistant *Enterococcus faecium* (VRE), Methicillin Resistant *Staphylococcus aureus* (MRSA) and *Escherichia coli* 0157:H7 the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 2 minutes. The surface may then be wiped dry with a clean towel.

** When used as directed, **AXEN® 30™ Disinfectant, Fungicidal & Virucidal Spray** provides protection from *Pseudomonas aeruginosa, Staphylococcus aureus* and *Salmonella cholerasuis* up to 24 hours after initial application. Do not clean treated surface after application if 24 hour protection is expected to be maintained

Fungus Control:
For effective control of fungus such as *Trichophyton mentagrophytes*, the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel. Re-apply when cleaning or when new growth appears.

Viral Control:
For elimination of Herpes Simplex Type I F(1) Strain the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 1 minute. The surface may then be wiped dry with a clean towel.

For the elimination of Influenza A Virus, Hong Kong strain, Rhinovirus R37 Strain 151-1, Polio Virus Type 2 Lansing Strain the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel.

Kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV): **Instructions for Cleaning and Decontamination Against HIV** on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids: **Personal Protection:** When handling items soiled with blood or body fluids, use appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** Apply **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** to area to be treated. The surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 30 seconds. The surface may then be wiped dry with a clean towel. **Disposal of Infectious Materials:** Blood and other body fluids should be autoclaved and disposed of according to federal, state *and local regulations for infectious waste disposal.*

STORAGE AND DISPOSAL	
Storage:	Do not contaminate water, food or feed by storage or disposal.
Disposal:	Do not reuse container. Rinse thoroughly before discarding in trash or recycling.

IN CASE OF EMERGENCY
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact CHEMTREC 1-800-424-9300 for emergency medical treatment information.

Additional language for front panel

Eliminates Odors
Eliminates – or – Kills 99.9999% of *Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella choleraesuis, and Listeria monocytogenes* in 30 seconds
Eliminates – or – Kills 99.9999% of *Staphylococcus aureus* in 30 seconds
Eliminates – or – Kills 99.9999% of *Salmonella choleraesuis* in 30 seconds
Eliminates – or – Kills 99.9999% of *Listeria monocytogenes* in 30 seconds
Eliminates – or – Kills 99.9999% of *Pseudomonas aeruginosa* in 30 seconds
Kills 99.9999% of germs in 30 seconds*
Kills germs in 30 seconds*
Eliminates – or - Kills common household germs
Eliminates – or - Kills common household germs including *Salmonella, Staphylococcus, Listeria, and E. coli.*
Eliminates – or - Kills *Salmonella, Staphylococcus, Listeria,* and *E. coli.*
Eliminates – or – Kills - Bacteria, Fungus and Virus*
No dulling residue
Disinfects without bleaching
No harsh chemical smell
Odorless.
Disinfects household surfaces
No Mixing Required
24 hour protection**

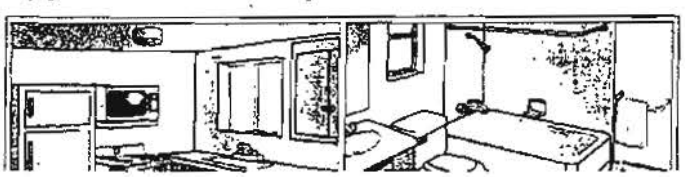
KEY: *= Refer to table

Alternate language for the back panel

Eliminates – or – Kills 99.9999% of *Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella choleraesuis, and Listeria monocytogenes* in 30 seconds
Eliminates – or – Kills 99.9999% of *Staphylococcus aureus* in 30 seconds
Eliminates – or – Kills 99.9999% of *Salmonella choleraesuis* in 30 seconds
Eliminates – or – Kills 99.9999% of *Listeria monocytogenes* in 30 seconds
Eliminates – or – Kills 99.9999% of *Pseudomonas aeruginosa* in 30 seconds
Kills 99.9999% of germs in 30 seconds*
Kills germs in 30 seconds*
24 hour protection**

KEY: *= Refer to table

Optional graphics for back of label (graphics are larger here than they will appear on the label)



Manufacturing process information may be entitled to confidential treatment

Laird's Regulatory Consultants, Inc

Over 28 years Experience and Expertise in The Regulation of Pesticide Products

February 5, 2003

Mr. Adam Hayward, PM 31
Environmental Protection Agency
Regulatory Management II
Antimicrobial Division (7510C)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Subject: AXEN 30
EPA FILE SYMBOL 72977-G
Revised labeling in accordance with your letter of 1/28/03
Ms. Drusilla Copeland Reviewer

Dear Mr. Hayward:

Per our letter referenced above, Under PRODUCT CHEMISTRY:

1. The correct spelling of the [redacted] ingredient on the CSF has been corrected. See revised CSF attached.
2. The stated purpose of the [redacted] Citric Acid on the CSF has been incorporated as [redacted] Active ingredient. See revised CSF attached.

Under UNACCEPTABLE LABEL CLAIMS, these items have been address in the order given as follows:

1. The bacteriostatic label claim has been deleted in accordance with paragraph 91-1 of Subdivision G per your request.
2. The verbiage "Ideal for use on. " which you state is considered to be a superlative, has been revised per you instructions
3. The phrase "Proven to eliminate bacteria...." Has been changed and referenced in the chart according to organisms.
4. The recommendation of a 2 minute wet contact time has been added.
5. The claim "virucidal" has been qualified by designating the strain of virus on page 2 of the revised label.
6. The statement "this product kills/ eliminates bacteria in 30 seconds has been removed to the chart with the designated strain of bacteria, which is demonstrated by the reviewed data, kill time of 30 seconds. Hence eliminating the broad range of bacteria coverage.
7. The verbiage "DISINFECT WITH CONFIDENCE" has been deleted from the back panel.

Olivia D. Laird President/Owner * 501 South Lincoln Avenue, Sterling, VA 20164-2024* Phone 703/471-6590 * Fax 703/471-6269

9. The names of all bacteria have been italicized per your request.
10. The statement "kills 99.9999% of bacteria in 30 seconds" and "kills 99.9999% bacteria in 30 seconds" has been redesignated according to the specific bacteria as shown in the test data. confirmation to this designation was confirmed in my telephone conversation with Mr. Hayward on 2/04/03.
10. Each specific specie/strain of bacteria, fungi and/or viruses to be eliminated has been designated per your recommendation.
11. The statement "Axen 30 .....lowest toxicity category" has been deleted under the heading.
12. We have deleted the statement "Toxicity Rating: Axen 30 Disinfectant, fungicidal & Virucidal Spray toxicity has been evaluated and placed in ..... Toxicity rating" under the Fast, Easy, Effective heading.
13. We have deleted the specified implied safety claims per your request.

The Formulator's Exemption Statement (EPA FORM 8570-27) is attached per your request.

Thank you for your prompt assistance in the registration of this product.

Sincerely,

Olivia D. Laird
President/Agent

Olivia D. Laird President/Owner * 501 South Lincoln Avenue, Sterling, VA 20164-2024* Phone 703/471-6590 * Fax 703/471-6269

United States Environmental Protection Agency
Washington, DC 20460

EPA Formulator's Exemption Statement

(40 CFR 152.85)

Form Approved
OMB No. 2070-0060
Approval expires 9-30-90

Applicant's Name and Address	EPA File Symbol/Registration Number
Innovative Medical Services ETI H2O, 1725 Gillespie Way El Cajon, CA 92020	72977-G
	Product Name Axen 30
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* February 5, 2003

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the following active ingredient(s):

Silver

Anhydrous Citric Acid

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the incorporation into the product *(during formulation or packaging)* of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula *(EPA Form 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula *(CSF) (EPA Form 8570-4)* referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Active Ingredient	Source	
	Product Name	Registration Number
Silver (ionic generated), Ag CAS No. 7440-22-4	Axenoh1	72977-1
Anhydrous Citric Acid CAS No. 77-92-9	Axenoh1	72977-1

Signature	Name and Title	Date
	Dolana Blount	February 5, 2003

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is a colorless, odorless broad spectrum antimicrobial disinfectant and deodorizer. Proven to eliminate bacteria, fungus and viruses* **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** should be used on non porous environmental hard surfaces in homes, hospitals, nursing homes, medical and dental clinics, laboratories, ambulance and patient transfer vehicles, funeral homes, hotels, restaurants, schools, day care facilities, offices, veterinary clinics, animal shelters, kennels, exercise facilities, beauty and barber shops, subways, trains, airplanes, ships, busses and other public transportation vehicles, locker rooms, kitchens, restrooms and other areas requiring control of microbial contamination.

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray has been formulated to disinfect hard, non porous environmental surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain) and objects such as walls, floors, counters, sinks, toilets, cabinets, tubs, showers, doorknobs, lights switch covers, telephones, appliances, stove tops, bed frames, wheelchairs, over-bed tables, examination tables and waste containers, tables, and chairs.

FAST, EASY, EFFECTIVE
General Information

* **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** demonstrated effective elimination of the following organisms under AOAC protocols:

Organism	Kill Time
Pseudomonas aeruginosa [1]	30 seconds
Staphylococcus aureus [1]	30 seconds
Salmonella choleraesuis [1]	30 seconds
Listeria monocytogenes [1]	30 seconds
Vancomycin resistant *Enterococcus faecium* [1]	2 minutes
Methicillin resistant *Staphylococcus aureus* [1]	2 minutes
Escherichia coli 0157:H7 [1]	2 minutes
Trichophyton mentagrophytes (Athlete's Foot Fungus)	10 minutes
HIV type 1- Strain HTLV IIIB [1]	30 seconds
Herpes Simplex Type 1 VR-733 F(1) Strain [2]	10 minute
Influenza A VR-544, Hong Kong strain [2]	10 minutes
Rhinovirus R37 VR-1147, Strain 151-1 [2]	10 minutes
Polio Type 2, VR-1002, Lansing Strain [2]	10 minutes

1 Evaluated in the presence of 5% organic soil.
2 Evaluated in the presence of 1% organic soil

Fungicidal Activity: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is effective against *Trichophyton mentagrophytes*, the Athlete's foot fungus. Use in locker rooms, dressing rooms, shower and bath areas, exercise facilities or any other hard, non-porous surface.

Deodorizes: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray reduces annoying odors caused by bacteria. Use to control odors in hospitals, nursing homes, public restrooms, animal kennels and barn stalls. In private homes use in the kitchen, bathroom, sink rooms and basements.

APPLICATION INSTRUCTIONS

Surfaces that are heavy soiled with organic matter must be pre-cleaned prior to using this product.

General Disinfection:
For general disinfection and elimination of bacteria such as *Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella cholerasuis, Listeria monocytogenes,* Vancomycin Resistant *Enterococcus faecium* (VRE) Methicillin Resistant *Staphylococcus aureus* (MRSA) and *Escherichia coli* 0157:H7 the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 2 minutes. The surface may then be wiped dry with a clean towel.

** When used as directed, **AXEN® 30™ Disinfectant, Fungicidal & Virucidal Spray** provides protection from *Pseudomonas aeruginosa, Staphylococcus aureus* and *Salmonella cholerasuis* up to 24 hours after initial application. Do not clean treated surface after application if 24 hour protection is expected to be maintained

Fungus Control:
For effective control of fungus such as *Trichophyton mentagrophytes,* the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel. Re-apply when cleaning or when new growth appears.

Viral Control:
For elimination of Herpes Simplex Type 1 F(1) Strain the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 1 minute. The surface may then be wiped dry with a clean towel.

For the elimination of Influenza A Virus, Hong Kong strain Rhinovirus R37 Strain 151-1, Polio Virus Type 2 Lansing Strain the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel.

Kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV): **Instructions for Cleaning and Decontamination Against HIV** on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids: **Personal Protection:** When handling items soiled with blood or body fluids, use appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** Apply **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** to area to be treated. The surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 30 seconds. The surface may then be wiped dry with a clean towel. **Disposal of Infectious Materials:** Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

STORAGE AND DISPOSAL	
Storage:	Do not contaminate water, food or feed by storage or disposal.
Disposal:	Do not reuse container. Rinse thoroughly before discarding in trash or recycling.

IN CASE OF EMERGENCY
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact CHEMTREC 1-800-424-9300 for emergency medical treatment information.

Additional language for front panel

Eliminates Odors
Eliminates – or – Kills 99.9999% of *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Listeria monocytogenes* in 30 seconds
Eliminates – or – Kills 99.9999% of *Staphylococcus aureus* in 30 seconds
Eliminates – or – Kills 99.9999% of *Salmonella choleraesuis* in 30 seconds
Eliminates – or – Kills 99.9999% of *Listeria monocytogenes* in 30 seconds
Eliminates – or – Kills 99.9999% of *Pseudomonas aeruginosa* in 30 seconds
Kills 99.9999% of germs in 30 seconds*
Kills germs in 30 seconds*
Eliminates – or - Kills common household germs
Eliminates – or - Kills common household germs including *Salmonella*, *Staphylococcus*, *Listeria*, and *E. coli*.
Eliminates – or - Kills *Salmonella*, *Staphylococcus*, *Listeria*, and *E. coli*.
Eliminates – or – Kills - Bacteria, Fungus and Virus*
No dulling residue
Disinfects without bleaching
No harsh chemical smell
Odorless
Disinfects household surfaces
No Mixing Required
24 hour protection**

KEY: *= Refer to table

Alternate language for the back panel

Eliminates – or – Kills 99.9999% of *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Listeria monocytogenes* in 30 seconds
Eliminates – or – Kills 99.9999% of *Staphylococcus aureus* in 30 seconds
Eliminates – or – Kills 99.9999% of *Salmonella choleraesuis* in 30 seconds
Eliminates – or – Kills 99.9999% of *Listeria monocytogenes* in 30 seconds
Eliminates – or – Kills 99.9999% of *Pseudomonas aeruginosa* in 30 seconds
Kills 99.9999% of germs in 30 seconds*
Kills germs in 30 seconds*
24 hour protection**

KEY: *= Refer to table

Optional graphics for back of label (graphics are larger here than they will appear on the label)

January 28, 2003

Ms. Olivia D. Laird
Consultant Agent
For
Innovative Medical Services
1725 Gillespie Way
El Cajon, California 92020

Dear Ms. Laird:

Subject: **Axen 30**
EPA File Symbol Number 72977-G
Application Dated: September 11, 2002

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is ***unacceptable*** for the following reasons:

Proposed Request:

- Application for new product registration

Data deficiencies:

Efficacy Review:

1. MRID Number 457572-02: The submitted efficacy data support the use of Axen 30 (EPA File Symbol 72977-G) as a disinfectant of hard, inanimate, non-porous surfaces contaminated with Methicillin-Resistant *Salmonella aureus* (MRSA) (ATCC #700698), Vancomycin-Resistant *Enterococcus faecium* (VRE) (ATCC 700221), *Escherichia coli* 0157:H7 (ATCC #43888) and/or *Listeria monocytogenes* (ATCC #19111) when used with a ten-minute exposure in the presence of a 5% organic soil load at 20°C. (The report lists the strain of *E. coli* tested as OH157. The correct strain for ATCC # 43888 is 0157:H7.) The product was effective against all tested strains of bacteria after a two-minute exposure. Although these studies were not conducted using the AOAC Germicidal Spray

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Products Test, they are acceptable because this product is not an aerosol spray.

2. MRID Number 457572-03: The submitted data support the use of Axen 30 as a disinfectant of hard, non-porous, inanimate surfaces that have been contaminated with *Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 15442) or *Salmonella choleraesuis* (ATCC 10708) when used with a ten-minute exposure in the presence of a 5% organic soil load at 20°C.

3. MRID Number 457572-04: The submitted data support the use of Axen 30 as a fungicide on hard, non-porous, inanimate surfaces that have been contaminated with *Trichophyton mentagrophytes* (ATCC #9533), when the product is used with a 10-minute exposure at 20°C in the presence of a 5% organic soil load. Both lots of the test material was effective against *Trichophyton mentagrophytes* (ATCC #9533) after a 10-minute exposure.

4. MRID Number 457572-05: This study is not acceptable. Bacteriostatic claims are permitted only against microorganisms identified as causing economic or aesthetic problems (e.g., odor-causing bacteria) in the presence of moisture, but not against microorganisms of public health concern. All data in support of residual self-sanitizing efficacy data should include a wear component commensurate with what is expected to be encountered during actual product use.

5. MRID Number 457572-06: The submitted efficacy data support the use of the product, Axen®, at a dilution of 30 ppm, as a virucide when tested against Influenza A virus, Hong Kong strain, (ATCC VR-544) on hard, non-porous, inanimate surfaces with a 1% soil load and a 10-minute exposure period at room temperature.

6. MRID Number 457572-07: The submitted efficacy data support the use of the product, Axen®, at a dilution of 30 ppm, as a virucide when tested against Human Immunodeficiency Virus type 1, Strain HTLV-III_B, on hard, non-porous, inanimate surfaces with a 5% organic soil load and a 30-second exposure period at room temperature.

7. MRID Number 457572-08: The submitted efficacy data support the use of the product, Axen®, at a dilution of 30 ppm, as a virucide when tested against Herpes simplex virus, type 1, (ATCC VR-733) on hard, non-porous, inanimate surfaces with a 1% organic soil load with one and ten minute exposures at room temperature.

8. MRID Number 457572-09: The submitted efficacy data support the use of the product, Axen®, at a dilution of 30 ppm, as a virucide when tested against Poliovirus type 2, Strain Lansing (ATCC VR-1002) on hard, non-porous, inanimate surfaces with a 1% organic soil load with a ten minute exposure at room temperature.

9. MRID Number 457572-10: The submitted efficacy data support the use of the product, Axen®, at a dilution of 30 ppm, as a virucide when tested against Rhinovirus type 37, strain 151-1, on hard, non-porous, inanimate surfaces with a 1% organic soil load with a ten minute exposure at room temperature.

Acute toxicity:

All of the acute toxicity data submitted in support of the subject proposed product is acceptable. The current acute toxicity database profile is as followings:

Table: Acute toxicity regulatory status of Axen® 30

Data Requirement	Means of Support	Status
Acute Oral Toxicity	MRID 450169-01, Cited	Acceptable, Tox Category IV
Acute Dermal Tox.	MRID 450169-04, Cited	Acceptable, Tox Category IV
Acute Inhalation Tox.	Waiver request	Waived, Tox Category IV
Eye Irritation	MRID 450165-01, Cited	Acceptable, Tox Category IV
Skin Irritation	MRID 450169-02, Cited	Acceptable, Tox Category IV
Skin Sensitization	MRID 450169-05, Cited	Acceptable, Non-sensitizer

Product Chemistry

The Confidential Statement of Formula of Formula (CSF) dated October 3, 2002 is acceptable with the following comments:

1. The correct spelling of the [redacted] ngredient on the CSF is [redacted]
2. The stated purpose of [redacted] citric acid on the CSF should be [redacted] Active Ingredient.

Labeling Comments:

The following label claims are acceptable:

1. The request to add labeling claims of Axen 30 being an effective disinfectant of hard, non-porous, inanimate surfaces contaminated with Methicillin-Resistant *Salmonella aureus* (MRSA) (ATCC #700698), Vancomycin-Resistant *Enterococcus faecium* (VRE) (ATCC 700221), *Escherichia coli* 0157:H7 (ATCC #43888) and/or *Listeria monocytogenes* (ATCC #19111) are approved. The submitted label lists the strain of *E. coli* as being "OH157." The statement also abbreviates the nomenclature of the organism. This must be changed from "*E. coli* OH157" to "*Escherichia coli* 0157:H7".

2. The request to add label claims that Axen 30 is an effective disinfectant against

Staphylococcus aureus (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 15442) or *Salmonella choleraesuis* (ATCC 10708) are approved. Axen 30 is approved as a hospital disinfectant.

3. The request to add labeling claims that Axen 30 is an effective fungicide on hard, non-porous, inanimate surfaces that have been contaminated with *Trichophyton mentagrophytes* (ATCC #9533) is approved.

4. The request to add labeling claims that Axen 30 is an effective virucide against Influenza A virus, Hong Kong strain (ATCC VR-544), is approved. The Agency recognizes that the lab tested the product with a 1% soil load. Soil loads are typically included in antimicrobial efficacy studies to obtain the designation of being effective in the presence of organic soil. An antimicrobial agent identified as a "one-step" cleaner-disinfectant, cleaner-sanitizer, or one intended to be effective in the presence of organic soil must be tested for efficacy by the appropriate method(s) which have been modified to include a representative organic soil such as 5% blood serum. However, you may retain the statement that this product was evaluated against Influenza A virus, Hong Kong strain (ATCC VR-544), in the presence of 1% organic soil.

5. The request to add labeling claims of Axen 30 being an effective virucide against Human Immunodeficiency Virus type 1, Strain HTLV-III_B in the presence of an organic soil load with a 10-minute exposure is approved.

6. The request to add labeling claims of Axen 30 being an effective virucide against Herpes simplex virus, type 1, ATCC Number VR-733, is approved. You may retain the statement that this product was evaluated against Herpes simplex virus, type 1, ATCC Number VR-733, in the presence of 1% organic soil.

7. The request to add labeling claims of Axen 30 being an effective virucide against Poliovirus, type 2, ATCC VR-733, is approved. You may retain the statement that this product was evaluated against Poliovirus, type 2, ATCC VR-733, in the presence of 1% organic soil.

8. The request to add labeling claims of Axen 30 being an effective virucide against Rhinovirus, type 37 (ATCC VR-1147, Strain 151-1), is approved. You may retain the statement that this product was evaluated against Rhinovirus, type 37, ATCC VR-1147, Strain 151-1, in the presence of 1% organic soil.

Unacceptable label claims:

1. The request to add labeling claims that Axen 30 is a bacteriostatic agent, or, that it will inhibit, check, eliminate or otherwise stop the growth of bacteria that are introduced to a surface that has been pre-treated with Axen 30 is denied. Again, bacteriostatic claims are permitted only against microorganisms identified as causing economic or aesthetic problems (e.g., odor-causing bacteria) in the presence of moisture, but not against microorganisms of public health concern.

No label claims stating that this product provides residual activity against bacteria are allowed on the product label. No labeling claims stating that this product continues to kill or eliminate bacteria after application are allowed on the product label. Please refer to Subdivision G, §91-2, (m).

2. Page 2 of the submitted label states that Axen 30 "... is ideal for use on ... contamination." Such statements are considered to be superlatives and are not allowed on the labels of EPA registered pesticides.

3. Page 2 of the submitted label states: "Proven to eliminate bacteria, fungus and viruses, contamination." This statement should refer to the table under General Information that lists the organisms that this product have been proven effective against.

4. Page 3 of the submitted label states: "For general disinfection and elimination of bacteria such as *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis* and *Listeria monocytogenes*, the surface must be completely wet with **Axen 30 Disinfectant, Fungicidal & Virucidal Spray** for 30 seconds." The EPA does not allow claims of 30-second disinfections. The product label must state that for disinfection, the treated surfaces must remain wet for **two minutes**.

5. The submitted label describes Axen 30 as being disinfectant, fungicidal and virucidal. According to Subdivision H, § 101-3, g, the unqualified label claim "virucidal" is not generally acceptable. The claim "virucidal" must be qualified by designating each specific virus against which the product has been tested and shown to be effective.

6. Statements claiming that this product kills or eliminates bacteria in 30-seconds are not allowed on the product label. This statement has not been proven for all species of bacteria that this product has been tested against.

7. The statement "disinfect with confidence" is not allowable. This could be taken to imply that one might not have confidence in other products. EPA/OPP/AD does not allow comparative labeling statements.

8. The names of all bacterial species listed on product labels should be italicized.

9. The statements "eliminates" or "kills 99.99999% of bacteria in 30 seconds", and, "eliminates" or "kills 99.9999% of bacteria in seconds" are not allowable. These statements must be removed from the product label. One reason for this is that Axen 30 was not always able to eliminate 99.9999% bacteria in 30 seconds.

10. The label states: Eliminates bacteria, fungus and virus. This statement is not allowable. The statement may be used if it refers to the specific species/strains of bacteria, fungi and/or viruses that this product was shown to eliminate.

11. Under the Direction For Use heading, delete the statement, "AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray demonstrated toxicity that placed it in Category IV, EPA's lowest toxicity category." This is a implied safety claim.

12. Under the Fast, Easy, Effective heading, delete the statement, "Toxicity Rating: AXEN® 30 Disinfectant, Fungicdal & Virucidal Spray toxicity has been evaluated and place in EPA toxicity Category IV -EPA's lowest toxicity rating." This is an implied Agency endorsement.

13. Under the heading "Additional language for front of label," delete the claims "No irritating fumes..odors," "No irritating perfumes," and "Disinfects without irritating fumes.. Odors." These are implied safety claims.

General comments:

In the future, when submitting data/studies/reports to the Agency for review, you must properly identify the test material used. It is understood that registrants often have products tested before a final product name is decided. However, this can be confusing in determining the proper test material identity. If the name of the test material used in the report is not exactly the same as the registration product, please state the relationship of the test material (the same product with a different name, a dilution of the test material, etc.) in a cover letter submitted with the test material.

In addition, you must submit a copy of EPA 8570-27 (Rev. 8-95) "Formulator's Exemption Statement." This form must be completely filled out, signed and dated.

Other comments:

For detailed information and consideration, refer to the enclosed EPA/AD Efficacy review dated January 16, 2003.

Please respond within 75 days from the date of this letter stating your intentions to comply with the information/data requests cited above. If no resubmission is received during the 75-day period, the application will be administratively withdrawn.

If you have any questions concerning this letter, please contact Adam Heyward at (703) 308-6422 or Drusilla Copeland at (703) 308-6224.

Sincerely,

Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

Stabilized Ionic Silver

Axen® 30

Disinfectant, Fungicide & Virucide

Disinfects and Deodorizes
Restaurants • Hospitals • Schools • Homes • Offices

KEEP OUT OF REACH OF CHILDREN

CAUTION

Active Ingredient	
Silver*	0.003%
Citric Acid	4.840%
Other Ingredients	95.157%
Total	100.000%

* Electrolytically generated Silver ions

Manufactured by ETI H2O
A Division of Innovative Medical Services
1725 Gillespie Way
El Cajon, CA 92020

EPA REG. No. 72977-#
EPA EST. No. 72977-CA-001

Net Vol. 5 gallon/1 gallon/40 oz./32 oz./ 16oz./ 5 oz./ 4 oz

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is a colorless, odorless broad spectrum antimicrobial disinfectant and deodorizer that continues to kill bacteria 24 hours after application. **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** demonstrated toxicity that placed it in Category IV, EPA's lowest toxicity category. Proven to eliminate bacteria, fungus and viruses, **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** is ideal for use on non-porous environmental hard surfaces in homes, hospitals, nursing homes, medical and dental clinics, laboratories, ambulance and patient transfer vehicles, funeral homes, hotels, restaurants, schools, day care facilities, offices, veterinary clinics, animal shelters, kennels, exercise facilities, beauty and barber shops, subways, trains, airplanes, ships, busses and other public transportation vehicles, locker rooms, kitchens, restrooms and other areas requiring control of microbial contamination.

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray has been formulated to disinfect hard, non-porous environmental surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain) and objects such as walls, floors, counters, sinks, toilets, cabinets, tubs, showers, doorknobs, lights switch covers, telephones, appliances, stove tops, bed frames, wheelchairs, over-bed tables, examination tables and waste containers, tables, and chairs,.

FAST, EASY, EFFECTIVE
General Information

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray demonstrated effective elimination of the following organisms under AOAC protocols:

Organism	Kill Time
Pseudomonas aeruginosa †	30 seconds
Staphylococcus aureus †	30 seconds
Salmonella cholerasuis †	30 seconds
Listeria monocytogenes †	30 seconds
Vancomycin resistant *Enterococcus faecium* †	2 minutes
Methicillin resistant *Staphylococcus aureus* †	2 minutes
E. coli OH157 †	2 minutes
Trichophyton mentagrophytes (Athlete's Foot Fungus)	10 minutes
HIV type 1- Strain HTLV IIIB †	30 seconds
Herpes Simplex Type 1 VR-733 F(1) Strain †	1 minute
Influenza A VR-544, Hong Kong strain ‡	10 minutes
Rhinovirus R37 VR-1147, Strain 151-1 †	10 minutes
Polio Type 2, VR-1002, Lansing Strain †	10 minutes

† Evaluated in the presence of 5% organic soil.
‡ Evaluated in the presence of 1% organic soil

Toxicity Rating: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray toxicity has been evaluated and placed in EPA Toxicity Category IV - EPA's lowest toxicity rating.

Residual Activity: Laboratory testing demonstrates that **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray**, when used as directed, remains effective in eliminating bacteria from hard surfaces up to 24 hours after application. (99.99% effective in 2 minutes)

Fungicidal Activity: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is effective against *Trichophyton mentagrophytes*, the Athlete's foot fungus. Use in locker rooms, dressing rooms, shower and bath areas, exercise facilities or any other hard, non-porous surface.

Deodorizes: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray reduces annoying odors caused by bacteria. Use to control odors in hospitals, nursing homes, public restrooms, animal kennels and barn stalls. In private homes, use in the kitchen, bathroom, sink rooms and basements.

APPLICATION INSTRUCTIONS

Surfaces that are heavy soiled with organic matter must be pre-cleaned prior to using this product.

General Disinfection:
For general disinfection and elimination of bacteria such as *Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella cholerasuis* and *Listeria monocytogenes*, the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 30 seconds. The surface may then be wiped dry with a clean towel.

Disinfection of Additional Organisms:
For disinfection where Vancomycin Resistant *Enterococcus faecium* (VRE), Methicillin Resistant *Staphylococcus aureus* (MRSA) and *E. coli* OH157 are a concern, the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 2 minutes. The surface may then be wiped dry with a clean towel.
When used as directed, **AXEN® 30™ Disinfectant, Fungicidal & Virucidal Spray** provides continued protection from bacteria up to 24 hours after initial application.

Fungus Control:
For effective control of fungus such as *Trichophyton mentagrophytes*, the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel. Re-apply when cleaning or when new growth appears.

Viral Control:
For elimination of Herpes Simplex Type 1 F(1) Strain the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 1 minute. The surface may then be wiped dry with a clean towel.

For the elimination of Influenza A Virus, Hong Kong strain, Rhinovirus R37 Strain 151-1, Polio Virus Type 2 Lansing Strain the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel.

Kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV): **Instructions for Cleaning and Decontamination Against HIV** on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids: **Personal Protection**: When handling items soiled with blood or body fluids, use appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** Apply **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** to area to be treated. The surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 30 seconds. The surface may then be wiped dry with a clean towel. **Disposal of Infectious Materials:** Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

STORAGE AND DISPOSAL	
Storage:	Do not contaminate water, food or feed by storage or disposal.
Disposal:	Do not reuse container. Rinse thoroughly before discarding in trash or recycling.

IN CASE OF EMERGENCY
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact CHEMTREC 1-800-424-9300 for emergency medical treatment information.

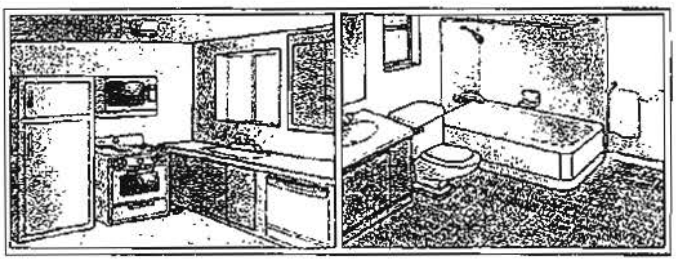
Additional language for front of label

Eliminates Odors
Eliminates – or – Kills 99.9999% of bacteria in 30 seconds
Eliminates – or – Kills 99.9999% of bacteria in seconds
Eliminates – or - Kills common household germs
Eliminates – or - Kills common household germs including Salmonella, Staphylococcus, Listeria, and E. coli.
Eliminates – or - Kills Salmonella, Staphylococcus, Listeria, and E. coli.
Eliminates – or - Bacteria, Fungus and Virus
No dull residue
Disinfects without bleaching
No harsh chemical smell
Odorless
No irritating fumes – or – odors
No irritating perfumes
Disinfects without irritating fumes – or – odors
Disinfects household surfaces
No Mixing Required
Disinfect with confidence

Alternate language for the back of the label

Eliminates – or – Kills 99.9999% of bacteria in 30 seconds
Eliminates – or – Kills 99.9999% of bacteria in seconds
Disinfect with confidence

Optional graphics for back of label (graphics are larger here than they will appear on the label)



KITCHEN BATHROOM

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

January 16, 2003

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 72977-G / Axen 30
DP Barcode: D286172

From: Ian Blackwell, Biologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Emily Mitchell, Team Leader 1/27/03
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

To: Adam Heyward, PM 34 / Drusilla Copeland
Regulatory Management Branch II
Antimicrobials Division (7510C)

Applicant: ETI H_2O, Inc.

Formulation From Label:

Active Ingredient(s)	% by wt
Silver	0.003
Citric Acid	4.840
Inert Ingredient(s)	95.157
Total	100.000

I **BACKGROUND:** ETI H_2O, Inc., has submitted a set of antimicrobial efficacy studies to support the registration of their product, "Axen 30". The MRID Numbers are 457572-02 thru 457572-10. The studies were conducted by Nelson Laboratories, Inc., and AppTec Laboratory Services.

These studies were primarily reviewed by the EPA contractor, DynCorp Systems & Solutions, LLC. The studies and the DynCorp report were briefly reviewed by EET/PSB/AD scientists to assure that they met Agency guidelines.

Axen® 30 (EPA Reg. No. 72977-G), is a new, as yet unregistered, ready-to-use product. The applicant requested to register the spray product as a disinfectant (bactericide, virucide, fungicide) for use on hard, non-porous, inanimate surfaces, including for use in homes, hospitals, restaurants, schools, and offices. The applicant indicated that the product is a "me-too" end-use product. The label claims that the product is effective against certain microorganisms in the presence of organic soil (1% or 5%). The label further claims that the product "remains effective in eliminating bacteria from hard surfaces up to 24 hours after application." Studies were conducted at Nelson Laboratories located at 6280 South Redwood Road in Salt Lake City, Utah 84123-6600 and AppTec Laboratory Services located at 2540 Executive Drive in St. Paul, Minnesota 55120.

This data package contained EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-35 (Data Matrix), nine studies (MRID Nos. 457572-02 through 457572-10), Statements of No Data Confidentiality Claims for all studies, and the proposed label.

The reports describe studies conducted on the product, Axen® (EPA Reg. No. 72977-2; 0.0012% silver) and state that the test material was a 30 ppm solution of Axenohl® (EPA Reg. No. 72977-1; 0.24% silver). Axenohl® is also referred to as the 2400 or 2410 ppm concentrate. Nothing in the reports or other parts of the data package actually states that 72977-G/Axen 30 is a 30 ppm solution of Axenohl. As there was a question of the test material identity, the study sponsor, Dolana Blount, was contacted. She faxed a letter to the study reviewer specifically stating that each of the test materials used in the reports submitted (MRID Numbers are 457572-02 thru 457572-10), once diluted, was equivalent to Axen 30. The concentrate used in these studies was Axenohl, 72977-1. (That letter is attached to this review.)

II **Use Directions**

The product is designed to be used for disinfecting hard, non-porous, inanimate surfaces such as walls, floors, counter tops, sinks, toilets, cabinets, tubs, showers, doorknobs, lights switch covers, telephones, appliances, stove tops, bed frames, wheelchairs, over-bed tables, examination tables and waste containers, tables, and chairs. Directions on the proposed label provided the following information

regarding preparation and use of the product as a disinfectant: Pre-clean surfaces that are heavily soiled. Completely wet surfaces with the product for the label-specified contact time (which varies depending upon the organism being targeted). Wipe surfaces dry with a clean towel.

The proposed label directions also included special instructions for cleaning and decontaminating against HIV-1 on pre-cleaned surfaces or objects previously soiled with blood/body fluids.

III Agency Standards for Proposed Claims

Confirmatory Efficacy Data Requirements - "Me-Too" Applications

A "me-too" application involves an old chemical (i.e., active ingredient) that has been previously registered for use as a pesticide and that is also the active ingredient present in the product proposed for registration (i.e., the product for which the current application is being submitted). DIS/TSS-5 states that products proposed for registration that are merely dilutions of a product already registered require only documentation of this identity and specific references to the supporting data developed for the original product. DIS/TSS-5 also states that confirmatory data must be produced when the test methodology used in support of the original supporting efficacy data (i.e., for the old chemical) are modified to include additional elements (e.g., organic soil load, shorter contact time). For hospital disinfectants, 10 carriers on each of two samples representing 2 different batches of product must be tested against *Salmonella choleraesuis* (ATCC 10708), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442) using either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products Test. Killing on all carriers is required. The above Agency standards are presented in DIS/TSS-5.

Note: The proposed label for the product, Axen® 30, indicates a 30 second contact time for *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*. The last accepted label (dated June 21, 2001) for the product, Axen®, indicates a 10 minute contact time for these three microorganisms.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Microorganisms)

Effectiveness of disinfectants against specific microorganisms other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products Test, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, but not including viruses, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products Test. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different batches. To support products labeled as "disinfectants" for specific microorganisms (other than

those microorganisms named in the above test methods), killing of the specific microorganism on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10^4 microorganisms survived the carrier-drying step. These Agency standards are also presented in DIS/TSS-1.

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products Test (for spray disinfectants) must be used in developing data for virucides intended for use upon dry inanimate, environmental surfaces (e.g., floors, tables, cleaned dried medical instruments). To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of two different batches of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi)

The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data derived from each of 2 product samples representing 2 different batches using the AOAC Fungicidal Test. The highest dilution that kills all fungal spores is the minimum effective concentration. In addition, the method indicates that conidia of required resistance survive a 10 minute exposure at 20°C to phenol dilution of 1:70, but not to one of 1:60. These Agency standards are presented in DIS/TSS-6 and AOAC Method 955.17.

Alternatively, the AOAC Use-Dilution Method may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. If the product is intended to be used as a spray product, the AOAC Germicidal Spray Products Test must be employed. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples representing 2 different batches must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required. These Agency standards are also presented in DIS/TSS-6.

IV Comments on the Submitted Efficacy Studies

1 MRID 457572-02: "AOAC Use Dilution - Carrier Confirmation," by Shelli A. Baxter. Study conducted at Nelson Laboratories, Inc. Study completion date – January 10, 2002. Lab Number – 197155. Protocol Number – 200135303-01.

This study was conducted against *Staphylococcus aureus* (MRSA) (ATCC 700698), *Enterococcus faecium* (VRE) (ATCC 700221), *Listeria monocytogenes* (ATCC 19111), and *Escherichia coli* OH157 (ATCC 43888). Two lots (Lot Nos. 2001-042-001 and 2001-005-001) of the product, Axenohl (EPA Registration Number 72977-1), were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. A 30 ppm solution of Axen® was prepared by diluting the 2410 ppm concentrate with 5% (w/w) citric acid in purified water. Equine blood serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers were immersed in a 48-54 hour old suspension of the test organism for 15 minutes, removed and shaken to remove excess culture, and dried for 40±2 minutes at 37±2°C. The carriers were exposed to 10 mL of the use solution at 20±0.5°C. Carriers were exposed for 30 second, 1 minute and 2 minute intervals. Following the exposure intervals, the carriers were removed from the use solution, shaken to remove residual product, transferred to tubes containing LETH, and shaken thoroughly. The culture tubes were incubated at 37±2°C for 2 days and then observed for the presence or absence of visible growth. Controls included neutralization verification, growth promotion of recovery media, and dried carrier counts.

Note: Although the report states that the test material was a dilution of Axen, information from the sponsor states that the test material was actually a dilution of Axenohl, 72977-1.

2 MRID Number 457572-03: "AOAC Use Dilution - Carrier Confirmation," by Shelli A. Baxter. Study conducted at Nelson Laboratories, Inc. Study completion date – January 9, 2002. Lab Number – 194972. Protocol Number 200126906-02.

This study was conducted against *Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 15442), and *Salmonella choleraesuis* (ATCC 10708). Two lots (Lot Nos. 2001-042-001 and 2001-005-001) of the product, Axenohl®, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. For both lots, 15 ppm, 20 ppm and 30 ppm solutions of Axenohl were prepared by diluting the 2410 ppm concentrate with 5% (w/w) citric acid in purified water. Equine blood serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel cylinder carriers were immersed in a 48-54 hour old suspension of the test

organism for 15 minutes, removed and shaken to remove excess culture, and dried for 40±2 minutes at 37±2°C. The carriers were exposed to 10 mL of the use solution at 20±0.5°C. Carriers were exposed for different intervals as follows:

Organism	Exposure Times		
	15 ppm Use Solution	20 ppm Use Solution	30 ppm Use Solution
Staphylococcus aureus	1, 5, and 10 minutes	1, 2, and 5 minutes	30 seconds, 1 and 2 minutes
Pseudomonas aeruginosa	1, 5, and 10 minutes	1, 2, and 5 minutes	30 seconds, 1 and 2 minutes
Salmonella choleraesuis	1, 5, and 10 minutes	1, 2, and 5 minutes	30 seconds, 1 and 2 minutes

Following the exposure intervals, the carriers were removed from the use solution, shaken to remove residual product, transferred to tubes containing Letheen Broth, and shaken thoroughly. The culture tubes were incubated at 37±2°C for 2 days and then observed for the presence or absence of visible growth. Controls included phenol resistance, neutralization verification, growth promotion of recovery media, and dried carrier counts.

3 MRID Number 457572-04: "Fungicidal Activity of a Disinfectant" by Shelli Baxter. Study conducted at Nelson Laboratories, Inc. Study completion date – January 11, 2002. Laboratory Sample ID – 197157. Protocol Number – 200124703-03.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two lots (Lot Nos. 2001-042-001 and 2001-005-001) of the product, Axenohl, were tested using the Fungicidal Activity of Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. A 30 ppm solution of Axenohl was prepared by diluting the 2410 ppm concentrate with 5% (w/w) citric acid in purified water. Five mL of use solution was placed into test tubes. A volume of 0.5 mL of the conidial suspension was placed in the first tube of use solution and shaken. After 30 seconds, 0.5 mL of the conidial suspension was added to a second tube. This was repeated at 30 second intervals until all tubes were inoculated. After 30 second, 1, 2, 5, and 10 minute intervals, a sample from each tube was removed and placed into 20 mL of glucose broth. The culture tubes were incubated at 27-29°C for 10 days and then observed for the presence or absence of visible growth. Controls included phenol resistance, neutralization verification, growth promotion of recovery media, and sterility.

4 MRID Number 457572-05: "Evaluation of Axen® for Residual Activity " by Shelli Baxter. Study conducted at Nelson Laboratories, Inc. Study completion date – February 8, 2002. Lab Sample ID – 197158. Protocol Number 200132009-02.

This study was conducted against *Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 15442), and *Salmonella choleraesuis* (ATCC 10708). Two lots (Lot Nos. 2001-042-001 and 2001-005-001) of the product, Axenohl, were tested. The report referenced the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. A 30 ppm solution of Axenohl was prepared by diluting the 2410 ppm concentrate with 5% (w/w) citric acid in purified water. Eighteen glass slides per organism, per lot, per time point were prepared. One mL of the use solution was applied to each glass slide. The use solution was spread over the entire slide with a clean towel. At 0, 1, 6, and 24 hours, 0.01 mL of the test culture was transferred onto the sterile test slides and spread uniformly over an approximate one inch by one inch area. Three slides per organism, per lot of product, were held for 30 seconds, 1 minute, and 2 minutes. After the exposure intervals, the slides were transferred into a bottle of lethene. One slide per organism, per time point, was extracted by shaking manually for 1 minute. A plate count was performed in triplicate. The remaining bottles and all plates were incubated for 48-54 hours at 37±2°C and observed for the presence or absence of visible growth. Controls included neutralization verification, growth promotion of recovery media, and initial counts.

Note: This study was conducted to support the claim that the product "remains effective in eliminating bacteria from hard surfaces up to 24 hours after application." In this study, the test material was applied **before** the application of the bacterial.

Note: Data were provided in triplicate (i.e., 3 data points) for both product lots, for each organism, and for each exposure interval. Only qualitative results (i.e., reported as growth or no growth) were provided for testing of the product against Lot No. 2001-005-001. Qualitative results also were provided for 2 of the 3 data points for testing of the product against Lot No. 2001-042-001. Quantitative results were provided for 1 of the 3 data points for testing of the product against Lot No. 2001-042-001 (i.e., the data point for the slide that was subjected to extraction).

5 MRID Number 457572-06: "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces" for Axen® 30, by Mary J. Miller. Study conducted at AppTec Laboratory Services. Study completion date – January 17, 2002. Project Number – 12465.

This study was conducted against Influenza A virus, Hong Kong strain (ATCC VR-544), using Rhesus monkey kidney cells (obtained from ViroMed Laboratories, Inc., Minneapolis, Minnesota) as the host system. Two lots (Lot Nos. 2001-042-001 and 2001-005-001) of the product, Axenohl, were tested according to an AppTec Laboratory Services protocol (Protocol No.

IMS01121301.FLU, copy not provided). The product was received, ready to use, from the applicant, and was identified as the 30 ppm use dilution of Axenohl®, a 2400 ppm concentrate. The stock virus titer contained a 1% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of three separate sterile glass Petri dishes. The virus films were dried at 20.1°C in a relative humidity of 46% for 20 minutes. For each lot of product, separate dried virus films were exposed to 2.0 mL of the use solution at 22°C. After 10 minutes of exposure, the plates were scraped with a cell scraper to re-suspend the contents and the virus-disinfectant mixture was passed through a Sephadex column. The filtrate was then titered by serial dilution in Eagles minimal essential medium (E-MEM) supplemented with 1% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL Fungizone. Rhesus monkey kidney cells were inoculated in quadruplicate with 0.1 mL of each dilution and incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The plates were scored periodically for 7 days for the absence or presence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included dried virus counts, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

6 MRID 457572-07: "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces" for Axen® 30, by Mary J. Miller. Study conducted at AppTec Laboratory Services. Study completion date – December 20, 2001. Project Number – 12305.

This study was conducted against Human Immunodeficiency Virus Type 1, Strain HTLV-III_B; (obtained from Advanced Biotechnologies, Inc., Columbia, Maryland), using MT-2 cell cultures (human CD4+ lymphocytes; propagated in-house; originally obtained from the National Cancer Institute, Frederick, Maryland) as the host system. No ATCC Number was provided for this strain of HTLV-III. Two lots (Lot Nos. 2001-042-001 and 2001-005-001) of the product, Axenohl, were tested according to an AppTec Laboratory Services protocol (Protocol No. IMS99111501.HIV, copy not provided). The product was received, ready to use, from the applicant, and was identified as the 30 ppm use dilution of Axenohl®, a 2400 ppm concentrate. The stock virus titer contained a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of three separate sterile glass Petri dishes. The virus films were air-dried at 17°C for 20 minutes, then incubated at 36-38°C for an additional 30 minutes. For each lot of product, separate dried virus films were exposed to 2.0 mL of the use solution at 17°C. After 30 seconds of exposure, the plates were scraped with a cell scraper to re-suspend the contents and the virus-disinfectant mixture was passed through a Sephadex column. The filtrate was then titered by serial dilution in RPMI 1640 supplemented with 15% (v/v) heat-inactivated fetal bovine serum, 2 mM L-glutamine, and 50 µg/mL gentamicin. MT-2 cells were inoculated in

quadruplicate with 0.2 mL of each dilution and incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The plates were scored periodically for 8 days for the absence or presence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included cytotoxicity, dried virus controls, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

7 MRID 457572-08: "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces" for Axen® 30, by Mary J. Miller. Study conducted at AppTec Laboratory Services. Study completion date – February 12, 2002. Project Number 12609.

This study was conducted against Herpes simplex virus type 1 (ATCC VR-733, F(1) Strain), using rabbit kidney cells (obtained from ViroMed Laboratories, Inc., Minneapolis, Minnesota) as the host system. Two lots (Lot Nos. 2001-042-001 and 2001-005-001) of the product, Axen®, were tested according to an AppTec Laboratory Services protocol (Protocol No. IMS01011002.HSV, copy not provided). The product was received, ready to use, from the applicant, and was identified as the 30 ppm use dilution of Axenohl®, a 2400 ppm concentrate. The stock virus titer contained a 1% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of six separate sterile glass Petri dishes. The virus films were dried at 10°C in a relative humidity of 50% for 25 minutes. For each lot of product, separate dried virus films were exposed to 2.0 mL of the use solution at 24°C. After both 1 minute and 10 minute exposures, the plates were scraped with a cell scraper to re-suspend the contents and the virus-disinfectant mixtures were passed through a Sephadex column. The filtrate was then titered by serial dilution in Eagles minimal essential medium (E-MEM) supplemented with 5% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL Fungizone. Rabbit kidney cells were inoculated in quadruplicate with 0.1 mL of each dilution and incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The plates were scored periodically for 7 days for the absence or presence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included cytotoxicity, dried virus controls, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

8 MRID Number 457572-09: "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces" for Axen® 30, by Mary J. Miller. Study conducted at AppTec Laboratory Services. Study completion date – February 12, 2002. Project Number – 12608.

This study was conducted against Poliovirus type 2 (ATCC VR-1002, Strain Lansing), using Vero cells (obtained from ViroMed Laboratories, Inc., Minneapolis, Minnesota) as the host system. Two lots (Lot Nos. 2001-042-001

and 2001-005-001) of the product, Axenohl, were tested according to an AppTec Laboratory Services protocol (Protocol No. IMS01011002.POL, copy not provided). The product was received, ready to use, from the applicant, and was identified as the 30 ppm use dilution of Axenohl, a 2400 ppm concentrate. The stock virus titer contained a 1% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of six separate sterile glass Petri dishes. The virus films were dried at 10°C in a relative humidity of 50% for 25 minutes. For each lot of product, separate dried virus films were exposed to 2.0 mL of the use solution at 23°C. After both 1 minute and 10 minute exposures, the plates were scraped with a cell scraper to re-suspend the contents and the virus-disinfectant mixtures were passed through a Sephadex column. The filtrate was then titered by serial dilution in Eagles minimal essential medium (E-MEM) supplemented with 5% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL Fungizone. Vero cells were inoculated in quadruplicate with 0.1 mL of each dilution and incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The plates were scored periodically for 7 days for the absence or presence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included cytotoxicity, dried virus controls, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

9 MRID Number 457572-10: "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces" for Axen® 30, by Mary J. Miller. Study conducted at AppTec Laboratory Services. Study completion date – February 12, 2002.

This study was conducted against Rhinovirus type 37 (ATCC VR-1147, Strain 151-1), using MRC-5 cells (human embryonic lung cells; obtained from ViroMed Laboratories, Inc., Minneapolis, Minnesota) as the host system. Two lots (Lot Nos. 2001-042-001 and 2001-005-001) of the product, Axenohl, were tested according to an AppTec Laboratory Services protocol (Protocol No. IMS01010402.R37, copy not provided). The product was received, ready to use, from the applicant, and was identified as the 30 ppm use dilution of Axenohl®, a 2400 ppm concentrate. The stock virus titer contained a 1% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of three separate sterile glass Petri dishes. The virus films were dried at 10.1°C in a relative humidity of 51% for 25 minutes. For each lot of product, separate dried virus films were exposed to 2.0 mL of the use solution at 22°C. After 10 minutes of exposure, the plates were scraped with a cell scraper to re-suspend the contents and the virus-disinfectant mixture was passed through a Sephadex column. The filtrate was then titered by serial dilution in Eagles minimal essential medium (E-MEM) supplemented with 10% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL Fungizone. MRC-5 cells were inoculated in quadruplicate with 0.1 mL of each dilution and incubated at 31-35°C in a

humidified atmosphere of 5-7% CO_2. The plates were scored periodically for 7 days for the absence or presence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included cytotoxicity, dried virus controls, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

V Results

Table 1. Antibacterial Activity of Axen Against *Staphylococcus aureus* (MRSA), *Enterococcus faecium* (VRE), *Listeria monocytogenes* and *Escherichia coli* 0157:H7.

MRID Number	Organism	Exposure Time	No. Exhibiting Growth/Total No. Tested		Dried Carrier Counts (CFU/carrier)
			Lot No. 2001-042-001	Lot No. 2001-005-001	
457572-02	*Staphylococcus aureus* (MRSA)	30 sec.	9/10	9/10	1×10^5
		1 min.	7/10	7/10	
		2 min. ✓	0/10	0/10	
	Enterococcus faecium (VRE)	30 sec.	0/10	2/10	1×10^4, 1×10^5
		1 min.	1/10	1/10	
		2 min.	0/10	0/10	
	Listeria monocytogenes	30 sec. ✓	0/10	0/10	1×10^4
		1 min.	0/10	0/10	
		2 min.	0/10	0/10 ✓	
	Escherichia coli 0157:H7	30 sec.	1/10	0/10	1×10^4, 1×10^5
		1 min.	0/10	1/10	
		2 min.	0/10	0/10 ✓	

Table 2. Test of 30 ppm Dilution of Axenohl Against Three Species of Bacteria

Axenohl Against Three Species of Bacteria					
MRID Number	Organism	Exposure Time	No. Exhibiting Growth/Total No. Tested		Microbes Initially Present (CFU/mL) at 30 ppm
			Lot No. 2001-042-001	Lot No. 2001-005-001	
457572-03	*Staphylococcus aureus*	30 sec.	0/10	0/10	1×10^5, 1×10^6
		1 min.	0/10	0/10	
		2 min.	0/10	0/10	
	Pseudomonas aeruginosa	30 sec.	0/10	0/10	1×10^4, 1×10^5
		1 min.	0/10	0/10	
		2 min.	0/10	0/10	
	Salmonella choleraesuis	30 sec.	0/10	0/10	1×10^5
		1 min.	0/10	0/10	
		2 min.	0/10	0/10	

Note: Results were also reported for a 15 and 20 ppm use solution of the product for *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Salmonella choleraesuis*. See MRID No. 457572-03.

Table 3. Test of a 30 ppm Dilution of Axen Against *Trichophyton mentagrophytes*

Axen Against *Trichophyton mentagrophytes*					
MRID Number	Organism	Exposure Time	Number Exhibiting Growth/ Total Number Tested		Viability (conidia/mL)
			Lot No. 2001-042-001	Lot No. 2001-005-001	
457572-04	*Trichophyton mentagrophytes*	30 sec	59/60	60/60	1.2×10^7
		1 min.	58/60	60/60	
		2 min.	54/60	57/60	
		5 min.	11/60	10/60	
		10 min.	0/60	0/60	

Table 4. MRID Number 457572-05: Residual Bactericidal Activity of Axen

Organism	Exposure Time	% Reduction/ Lot No. 2001-042-001				Microbes Initially Present (CFU/mL) at 0, 1, 6, 24 Hours
		0 Hour	1 Hour	6 Hours	24 hours	
Staphylococcus aureus	0.5 min.	99.7	99.8	99.993	99.6	7.7×10^3 7.7×10^3 3.2×10^4 3.2×10^4
	1 min.	99.99	99.94	99.997	99.96	
	2 min.	99.99	99.97	99.96	99.99	
Salmonella choleraesuis	0.5 min.	64	99.4	81	83	1.1×10^5 1.1×10^5 3.4×10^4 3.4×10^4
	1 min.	99.5	99.997	99	93	
	2 min.	99.99	99.996	99.7	>99.997	
Pseudomonas aeruginosa	0.5 min.	99	99.7	74	>99.998	5.7×10^4 5.7×10^4 4.2×10^4 4.2×10^4
	1 min.	99.8	99	99.93	99.990	
	2 min.	99.99	99.9	99.97	>99.998	

Table 5. Virucidal Efficacy of Axen at 30 ppm.

MRID Number	Organism	Results			Dried Virus Control
			Lot No. 2001-042-001	Lot No. 2001-005-001	
457572-06	Influenza A virus, strain Hong Kong	10^{-1} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	$10^{5.25}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
457572-07	Human Immuno-deficiency Virus Type 1	10^{-1}	Cytotoxicity present	Cytotoxicity present	$10^{5.25}$ $TCID_{50}$/0.2 mL
		10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/0.2 mL	$\leq 10^{1.5}$	$\leq 10^{1.5}$	
		Log reduction	≥ 3.75 $\log_{10}$	≥ 3.75 $\log_{10}$	
457572-08 Contact Time: 1 min.	Herpes simplex virus type 1	10^{-1} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	$10^{8.0}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
457572-09 Contact Time: 10 minutes.	Poliovirus type 2, strain Lansing	10^{-1} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	$10^{6.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
457572-10	Rhinovirus type 37, strain 151-1	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{5.0}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	

VI Conclusions

1 MRID Number 457572-02: The submitted efficacy data support the use of Axen 30 (EPA File Symbol 72977-G) as a disinfectant of hard, inanimate, non-porous surfaces contaminated with Methicillin-Resistant *Salmonella aureus* (MRSA) (ATCC #700698), Vancomycin-Resistant *Enterococcus faecium* (VRE) (ATCC 700221), *Escherichia coli* 0157:H7 (ATCC #43888) and/or *Listeria monocytogenes* (ATCC #19111) when used with a ten-minute exposure in the presence of a 5% organic soil load at 20°C. (The report lists the strain of *E. coli* tested as OH157. The correct strain for ATCC # 43888 is 0157:H7.) The product was effective against all tested strains of bacteria after a two-minute exposure. Although these studies were not conducted using the AOAC Germicidal Spray Products Test, they are acceptable because this product is not an aerosol spray.

2 MRID Number 457572-03: The submitted data support the use of Axen 30 as a disinfectant of hard, non-porous, inanimate surfaces that have been contaminated with *Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 15442) or *Salmonella choleraesuis* (ATCC 10708) when used with a ten-minute exposure in the presence of a 5% organic soil load at 20°C.

3 MRID Number 457572-04: The submitted data support the use of Axen 30 as a fungicide on hard, non-porous, inanimate surfaces that have been contaminated with *Trichophyton mentagrophytes* (ATCC #9533), when the product is used with a 10-minute exposure at 20°C in the presence of a 5% organic soil load. Both lots of the test material were effective against *Trichophyton mentagrophytes* (ATCC #9533) after a 10-minute exposure.

4 MRID Number 457572-05: This study is not acceptable. Bacteriostatic claims are permitted only against microorganisms identified as causing economic or aesthetic problems (e.g., odor-causing bacteria) in the presence of moisture, but not against microorganisms of public health concern. All data in support of residual self-sanitizing efficacy data should include a wear component commensurate with what is expected to be encountered during actual product use.

5 MRID Number 457572-06: The submitted efficacy data support the use of the product, Axen®, at a dilution of 30 ppm, as a virucide when tested against Influenza A virus, Hong Kong strain, (ATCC VR-544) on hard, non-porous, inanimate surfaces with a 1% soil load and a 10-minute exposure period at room temperature.

6 MRID Number 457572-07: The submitted efficacy data support the use of the product, Axen®, at a dilution of 30 ppm, as a virucide when tested against Human Immunodeficiency Virus type 1, Strain HTLV-III_B, on hard, non-porous, inanimate surfaces with a 5% organic soil load and a 30-second exposure period at room temperature.

7 MRID Number 457572-08: The submitted efficacy data support the use of the product, Axen®, at a dilution of 30 ppm, as a virucide when tested against Herpes simplex virus, type 1, (ATCC VR-733) on hard, non-porous, inanimate surfaces with a 1% organic soil load with one and ten minute exposures at room temperature.

8 MRID Number 457572-09: The submitted efficacy data support the use of the product, Axen®, at a dilution of 30 ppm, as a virucide when tested against Poliovirus type 2, Strain Lansing (ATCC VR-1002) on hard, non-porous, inanimate surfaces with a 1% organic soil load with a ten minute exposure at room temperature.

9 MRID Number 457572-10: The submitted efficacy data support the use of the product, Axen®, at a dilution of 30 ppm, as a virucide when tested against Rhinovirus type 37, strain 151-1, on hard, non-porous, inanimate surfaces with a 1% organic soil load with a ten minute exposure at room temperature.

VII Recommendations

1 We ask that whenever the registrant submits data/studies/reports to PSB/AD for review, they properly identify the test material used. It is understood that registrants often have products tested before a final product name is decided on. However, it wastes much valuable time for reviewers to have to determine the proper test material identity when it is something that should be one of the most basic parts of a data submission. If the name of the test material used in the report is not exactly the same as the registration product, the registrant may state the relationship of the test material (the same product with a different name, a dilution of the test material, etc.) in a cover letter submitted with the test material.

2 The request to add labeling claims of Axen 30 being an effective disinfectant of hard, non-porous, inanimate surfaces contaminated with Methicillin-Resistant *Salmonella aureus* (MRSA) (ATCC #700698), Vancomycin-Resistant *Enterococcus faecium* (VRE) (ATCC 700221), *Escherichia coli* 0157:H7 (ATCC #43888) and/or *Listeria monocytogenes* (ATCC #19111) is approved. The submitted label lists the strain of *E. coli* as being "OH157". The statement also abbreviates the nomenclature of the organism. This should be changed from "*E. coli* OH157" to "*Escherichia coli* 0157:H7".

3 The request to add label claims that Axen 30 is an effective disinfectant against *Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 15442) or *Salmonella choleraesuis* (ATCC 10708) is approved. Axen 30 is approved as a hospital disinfectant.

4 The request to add labeling claims that Axen 30 is an effective fungicide on hard, non-porous, inanimate surfaces that have been contaminated with *Trichophyton mentagrophytes* (ATCC #9533) is approved.

5 The request to add labeling claims that Axen 30 is a bacteriostatic agent, or, that it will inhibit, check, eliminate or otherwise stop the growth of bacteria that are introduced to a surface that has been pre-treated with Axen 30 is denied. Again, bacteriostatic claims are permitted only against microorganisms identified as causing economic or aesthetic problems (e.g., odor-causing bacteria) in the presence of moisture, but not against microorganisms of public health concern. **No label claims stating that this product provides residual activity against bacteria are allowed on the product label.** No labeling claims stating that this product continues to kill or eliminate bacteria after application are allowed on the product label. Please refer to Subdivision G, §91-2, (m).

6 The request to add labeling claims that Axen 30 is an effective virucide against Influenza A virus, Hong Kong strain (ATCC VR-544), is approved. PSB/AD recognizes that the lab tested the product with a 1% soil load. Soil loads are typically included in antimicrobial efficacy studies to obtain the designation of being effective in the presence of organic soil. An antimicrobial agent identified as a "one-step" cleaner-disinfectant, cleaner-sanitizer, or one intended to be effective in the presence of organic soil must be tested for efficacy by the appropriate method(s) which have been modified to include a representative organic soil such as 5% blood serum. However, the registrant may retain the statement that this product was evaluated against Influenza A virus, Hong Kong strain (ATCC VR-544), in the presence of 1% organic soil.

7 The request to add labeling claims of Axen 30 being an effective virucide against Human Immunodeficiency Virus type 1, Strain HTLV-III_B, in the presence of an organic soil load with a 10-minute exposure is approved.

8 The request to add labeling claims of Axen 30 being an effective virucide against Herpes simplex virus, type 1, ATCC Number VR-733, is approved. The registrant may retain the statement that this product was evaluated against Herpes simplex virus, type 1, ATCC Number VR-733, in the presence of 1% organic soil.

9 The request to add labeling claims of Axen 30 being an effective virucide against Poliovirus, type 2, ATCC VR-733, is approved. The registrant may retain the statement that this product was evaluated against Poliovirus, type 2, ATCC VR-733, in the presence of 1% organic soil.

10 The request to add labeling claims of Axen 30 being an effective virucide against Rhinovirus, type 37 (ATCC VR-1147, Strain 151-1), is approved. The registrant may retain the statement that this product was evaluated against Rhinovirus, type 37, ATCC VR-1147, Strain 151-1, in the presence of 1% organic soil.

11 Page 2 of the submitted label states that Axen 30 "... is ideal for use on ... contamination." Such statements are considered to be superlatives and are not allowed on the labels of EPA registered pesticides.

12 Page 2 of the submitted label states: "Proven to eliminate bacteria, fungus and viruses, ...contamination." This statement should refer to the table under General Information that lists the organisms that this product have been proven effective against.

13 Page 3 of the submitted label states: "For general disinfection and elimination of bacteria such as *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis* and *Listeria monocytogenes*, the surface must be completely wet with **Axen 30 Disinfectant, Fungicidal & Virucidal Spray** for 30 seconds." The EPA does not allow claims of 30-second disinfections. The product label must state that for disinfection, the treated surfaces must remain wet for **two minutes**.

14 The submitted label describes Axen 30 as being disinfectant, fungicidal and virucidal. According to Subdivision H, § 101-3, g, the unqualified label claim "virucidal" is not generally acceptable. The claim "virucidal" must be qualified by designating each specific virus against which the product has been tested and shown to be effective.

15 Statements claiming that this product kills or eliminates bacteria in 30-seconds are not allowed on the product label. This statement has not been proven for all species of bacteria that this product has been tested against.

16 The statement "disinfect with confidence" is not allowable. This could be taken to imply that one might not have confidence in other products. EPA/OPP/AD does not allow comparative labeling statements.

17 The names of all bacterial species listed on product labels should be italicized.

18 The statements "eliminates" or "kills 99.99999% of bacteria in 30 seconds", and, "eliminates" or "kills 99.9999% of bacteria in seconds" are not allowable. These

statements must be removed from the product label. One reason for this is that Axen 30 was not always able to eliminate 99.9999% bacteria in 30 seconds.

19 The label states: Eliminates bacteria, fungus and virus. This statement is not allowable. The statement may be used if it refers to the specific species/strains of bacteria, fungi and/or viruses that this product was shown to eliminate.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 31, 2002

MEMORANDUM

Subject: Data Package D286176
Axen® 30, EPA File Symbol 72977-G

From: Wallace Powell, Biologist
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen P. Hicks, Team Leader
Chemistry/Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

To: Adam Heyward, Product Manager, Team 34
Drusilla Copeland, Team Reviewer, Team 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

BACKGROUND

The applicant, ETI H2O, Inc. (as represented by an agent), has submitted a package for registration of the subject product, Axen® 30. The product is labeled as a hard surface disinfectant spray containing the active ingredients silver (as electrolytically generated ions, 0.003 percent of the formulation by weight) and citric acid (4.84 percent by weight). The product is a pump spray (rather than an aerosol spray), as confirmed to Wallace Powell of Product Science Branch (PSB) in a 12/30/2002 telephone conversation with Olivia Laird of Laird's Regulatory Consultants, Inc., agent for the applicant; and as confirmed by the absence of any apparent propellant in the product statement of formula. For acute oral and acute dermal toxicity, skin irritation, and skin sensitization, the applicant is citing studies previously accepted for Axenohl®, EPA Registration No. 72977-1. For acute inhalation toxicity, the applicant is requesting a waiver based on a waiver justification that supported a previous waiver for Axen®, EPA Reg. No. 72977-2. For eye irritation, the applicant is citing a study previously accepted for Axen®. As noted below, these acute inhalation toxicity and eye irritation data citations are amended ones, as the applicant's original citations for these two requirements appeared faulty and have since been amended in a 12/30/2002 letter.

DISCUSSION AND RECOMMENDATION

Acute oral, acute dermal toxicity, skin irritation and sensitization

The study citations for acute oral and acute dermal toxicity, skin irritation, and skin sensitization are acceptable. The study MRIDs are listed in the table below ("Acute toxicity regulatory status of Axen® 30"). The studies were conducted on Axenohl® (EPA Reg. No. 72977-1), which has similar components but is much more concentrated than Axen® 30 and can be considered useful as a worst-case comparison substance. The studies were accepted by PSB (02/03/2001 review, Data Package D270802) in support of Tox Category IV for these five acute effects.

Eye irritation and acute inhalation toxicity

On 12/30/2002, Wallace Powell of PSB made a telephone call to Olivia Laird, consultant for ETI H2O, to let her know that the eye irritation and acute inhalation data citations in the applicant's 08/21/2002 Data Matrix were not applicable. (The MRID entries correspond to Product Chemistry data.) After the phone call, Ms. Laird submitted a 12/30/2002 letter by Fax to indicate the intention to rely on the same eye irritation and acute inhalation data support that had previously been accepted for Axen®, EPA Reg. No. 72977-2. For *eye irritation*, that support was in the form of a submitted study, MRID 450165-01, conducted on Axen® and accepted by PSB on 05/08/2000 (Data Package D263138) in support of Tox Category IV. For *acute inhalation toxicity*, that support was in the form of a waiver request which was accepted by PSB on 06/21/2001 (Data Package D274823). The reasons for the acute inhalation waiver can essentially be restated as follows on behalf of Axen® 30 because of its close similarity to Axen®:

- Based on product formulation, the acute toxicity of Axen® 30 is expected to be similar to what the citric acid component would be, at its concentration of 4.8%. This is far less than the concentration which the Citric Acid Reregistration Eligibility Document (RED) characterizes as mild with respect to systemic acute toxicity for any expected exposures from pesticide uses. (The Citric Acid RED cites no MRIDs in this regard, so data compensation is not applicable.)

- Based on studies conducted on the applicant's Axenohl® (EPA Reg. No. 72977-1, having similar components but much more concentrated than Axen® 30) – which were accepted by PSB in support of Tox Category IV for acute oral and acute dermal toxicity and skin irritation (02/03/2001 PSB review, Data Package D270802) – the acute effects of Axen® 30 are generally expected to be quite mild.

- Although there is some potential for inhalation exposure, it is not expected to be great: no aerosol application appears on the product label, and the product is not expected to be significantly volatile. Though this is not sufficient waiver justification in itself, it is somewhat meaningful in relation to the above comments.

PSB considers Axen® (EPA Registration No. 72977-2) and Axen® 30 to be substantially similar to each other, such that acute toxicity and irritation data accepted for the one product can be accepted for the other. Although the silver concentration in Axen® 30 is 0.003 percent, versus the 0.0012 percent in Axen®, this would make little if any practical difference in acute toxicity or irritation levels, because these minuscule silver concentrations are not of significant concern in regard to acute effects.

Therefore, the eye irritation and acute inhalation data support proposed in Ms. Laird's 12/30/2002 letter are acceptable. (If the Product Manager requires a resubmitted Data Matrix form with entries for eye irritation MRID 450165-01 and acute inhalation Waiver Request, the revised form would not need PSB review.)

Summary

The acute toxicity regulatory profile is listed in the following table.

Table: Acute toxicity regulatory status of Axen® 30

Data Requirement	Means of Support	Status
Acute Oral Toxicity	MRID 450169-01, Cited	Acceptable, Tox Category IV
Acute Dermal Tox.	MRID 450169-04, Cited	Acceptable, Tox Category IV
Acute Inhalation Tox.	Waiver request	Waived, Tox Category IV
Eye Irritation	MRID 450165-01, Cited	Acceptable, Tox Category IV
Skin Irritation	MRID 450169-02, Cited	Acceptable, Tox Category IV
Skin Sensitization	MRID 450169-05, Cited	Acceptable, Non-sensitizer

Product Labeling

No first aid statements are required in the proposed label draft label. (No identifier date was found, but the label appears to be part of the 10/03/2002 submission package.)

The proposed human-hazard precautionary labeling (limited to the child-hazard warning and the signal word CAUTION) are acceptable except that the following statements should be deleted:

- Under the DIRECTIONS FOR USE heading, delete the statement, "AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray demonstrated toxicity that placed it in Category IV, EPA's lowest toxicity category." This may be considered an implied safety claim. (Also, strictly speaking, this product is not the one that "demonstrated" Category IV toxicity.)

- Under the FAST, EASY, EFFECTIVE heading, delete the statement, "Toxicity Rating: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray toxicity has been evaluated and placed in EPA Toxicity Category IV - EPA's lowest toxicity rating." This may be considered an implied Agency endorsement.

- Under the heading "Additional language for front of label," delete the claims "No irritating fumes ... odors," "No irritating perfumes," and "Disinfects without irritating fumes ... odors." These may be considered implied safety claims.

Although these opinions about an "implied Agency endorsement" and "implied safety claims" might be deemed beyond the scope of a PSB review, note that they are based on consultation with one of the Product Managers.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 21, 2001

MEMORANDUM

Subject: D274823
AXEN, EPA File Symbol 72977-E

From: Wallace Powell, Biologist
Product Science Branch
Antimicrobials Division (7510C)

Thru: Karen P. Hicks, Team Leader
Chemistry/Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

To: Marshall Swindell, Product Manager, Team 33
Martha Terry, Team Reviewer, Team 33
Regulatory Management Branch I
Antimicrobials Division (7510C)

BACKGROUND

The applicant, ETI H_2O, Inc. (as represented by an agent), has submitted a package for registration of the subject product, AXEN. The package includes requests for waiver of acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, skin irritation, and skin sensitization data. The acute inhalation waiver requests is accompanied by a submitted rationale. The other four waiver requests are accompanied by citation of the agency's Citric Acid Reregistration Eligibility Decision (RED) document. For the eye irritation requirement, a study on AXEN (MRID 450165-01) was previously accepted.

AXEN is labeled as a hard surface disinfectant pump spray product containing the active ingredients silver (as ions, 0.0012% of the formulation by weight) and citric acid (4.84% of the formulation by weight).

RECOMMENDATION

Eye irritation

Eye irritation has been assigned to Category IV, based on MRID 450165-01 (refer to 05/08/00 Product Science Branch memorandum, Data Package D263138).

Acute oral and acute dermal toxicity, skin irritation

The applicant has cited the Citric Acid RED to support these data requirements. Based on the product formulation, the acute toxicity and skin irritation of AXEN is expected to be similar to what the citric acid component would be, at its concentration of 4.8%. This is far less than the concentration which the Citric Acid RED characterizes as mild with respect to systemic acute toxicity. Therefore, Product Science Branch (PSB) recommends Category IV for acute oral and acute dermal toxicity.

The RED characterizes technical grade citric acid as a moderate skin irritant. However, because 4.8% is far less concentration than technical grade and because the submitted eye irritation study for AXEN indicates eye irritation Category IV, skin irritation Category IV is also expected.

As further support for Category IV, note that in a 03/15/01 agency letter, the applicant's other product Axehnol (EPA File Symbol 72977-R) was assigned Toxicity Category IV for acute oral and acute dermal toxicity and for skin irritation, based on submitted studies (refer to 02/03/01 PSB memorandum, Data Package D270802). AXEN has similar components but is far less concentrated than Axehnol.

Skin sensitization

PSB recommends classification of AXEN as Non-sensitizer. The applicant has cited the Citric Acid RED document, which of course indicates no concern regarding skin sensitization for that chemical. The small set of additional chemicals in AXEN are not expected to add significant skin sensitization potential at the concentrations present.

Acute inhalation toxicity

The request for waiver of acute inhalation toxicity data is acceptable, for the following reasons.

- Based on the product formulation, the acute toxicity of AXEN is expected to be similar to what the citric acid component would be, at its concentration of 4.8%. This is far less than the concentration which the Citric Acid RED characterizes as mild with respect to systemic acute toxicity.

- Based on the Category IV data mentioned above for Axehnol (EPA File Symbol 72977-R), which is more concentrated than AXEN, the acute toxicity of AXEN is expected to be quite mild.

- Although some inhalation exposure is expected, it is not expected to be particularly great, as the applicant points out. (No aerosol application appears on the label, and the product is not expected to be highly volatile.) This of course is not sufficient waiver justification in itself, but it is somewhat meaningful in association with the above comments.

Summary

An acute toxicity regulatory status for the subject product is summarized in the following table.

Data Requirement	Means of Support	Status/ Acute Tox. Category
Acute Oral Toxicity	Waiver request and RED citation	Waived/ IV
Acute Dermal Toxicity	Waiver request and RED citation	Waived/ IV
Acute Inhalation Tox.	Waiver request and RED citation	Waived/ IV
Eye Irritation	Previously submitted study, MRID 450165-01	Acceptable/ IV
Skin Irritation	Waiver request and RED citation	Waived/ IV
Skin Sensitization	Waiver request and RED citation	Waived/ Non-sensitizer

Product Labeling

The human-hazard precautionary statements on the proposed product label identified as "revision May 2, 2001," are acceptable. (They are "KEEP OUT OF REACH OF CHILDREN" and "CAUTION".) No first aid statements are required.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

October 30, 2002

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Axen 30

DP Barcode: D286173 **Reg. No. Or File Symbol: 72977-G**
Manufacturing-use [ ] OR **End-use Product [X]**

TO: Adam Heyward PM 34 / Drusilla Copeland, Team Reviewer
Regulatory Management Branch II
Antimicrobials Division (7510C)

FROM: Robert A. Turpin, Chemist RT
Product Science Branch, CT Team
Antimicrobials Division (7510C)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C)

10/3/02

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Product Formulation

Active Ingredient(s)	**% by wt.**
Citric acid	4.840
Silver	0.003

BACKGROUND: The applicant has submitted a "Me-Too" application for its product, Axen 30. The product is similar to EPA Reg. Nos. 72977-1 and 72977-2. In support of the application is submitted a Confidential Statement of Formula, a draft label, a data matrix, and studies MRID #457572-01 and MRID #457715-01. The Product Science Branch has performed the primary review.

FINDINGS:

1. The spelling of the [redacted] ingredient on the Confidential Statement of Formula is incorrect. The correct spelling is [redacted]

2. The stated purpose of [redacted] citric acid on the Confidential Statement of Formula should be [redacted] Active Ingredient.

3. The certified limits of the ingredients listed on the Confidential Statement of Formula are acceptable to the Agency.

4. The Confidential Statement of Formula of the subject product is acceptable with the above noted comments.

[redacted] The chemical data submitted contained in MRID #s 457572-01, and 457715-01 are acceptable to the Agency.

RECOMMENDATIONS: None.

Manufacturing process information may be entitled to confidential treatment

Inert ingredient information may be entitled to confidential treatment

[redacted]

PRODUCT CHEMISTRY REVIEW

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

- Non-integrated formulation system [X]
  - Are all TGAIs used registered? Yes [X] No [ ]
- Integrated formulation system [ ]
- if "ME-TOO", specify EPA Reg. # of existing product:

4b. Clearance of inerts for non-food or food use:
Cleared for food use under 40 CFR §180.1001: Yes [ ] No [X] NA[ ]

4c. Physical state of product: Liquid

4d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830, Part B
Yes [X] No [ ]

4h. NCs and CLs are acceptable: Yes [X] No [ ] Not acceptable [ ]

4i. Active ingredient (s)	NC	LCL	UCL
A. Silver	0.003%	0.0027%	0.0033%
B. Citric acid	4.840%	4.599%	5.093%

4j. For products produced by an integrated formulation system:

- All impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- All impurities of $\geq 0.1\%$ in the product have been identified?
  Yes [ ] No [ ] Not applicable [X]

5. PRODUCT LABEL

5a. The active ingredients statement (chemical IDs and NC] is consistent with the CONFIDENTIAL STATEMENT OF FORMULA? Yes [X] No [ ]

5b. The formulation contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- Sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

5c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?
Yes [ ] No [ ] Not applicable [X]

5e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses? Yes [X] No [ ] Not on label

5f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information)?
Yes [ ] No [X]

2. **PRODUCT CHEMISTRY (830 Series, Part B)**

Guideline	Acceptance of Information	MRID No.
830.1550[1] Product Identity	A	457715-01
830.1600 Description of Materials	A	457715-01
830.1620 Production Method[2]	NA	
830.1650 Formulation process[3]	A	457572-01
830.1670 Formation of impurities[4]	A	457572-01
830.1700 Preliminary Analysis[5]	NA	
830.1750 Certified Limits[6]	A	457715-01
830.1800 Analytical Method[7]	A	451610-01

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

---

[1]See Confidential Appendix A for additional information

[2]For MP/EP products produced by an integrated formulation system.

[3]For products from a TGAI or MP.

[4]May be waived unless actual/possible impurities are of toxicological concern.

[5]Five batch analysis required for products produced by an integrated formulation system.

[6]If different from standard CIs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

6b. Physical/Chemical Properties*	Acceptance of data	Value or qualitative description	MRID No.
830.6302 Color	A	Colorless	457715-01
830.6303 Physical state	A	Liquid	457715-01
830.6303 Odor	A	Odorless	457715-01
830.7200 Melting point	NA		
830.7220 Density/Relative density/bulk density	A	1.018	457715-01
830.7000 pH[1]	A	1.79	457715-01
830.6314 Oxidation/Reduction	A	Can be reduced electronically and has some weak oxidizing potential of no practical significance	457715-01
830.6315 Flammability	A	Not flammable	457715-01
830.6317 Storage stability	A	Stable	456232-01
830.7100 Viscosity	NA		
830.6319 Miscibility[2]	NA		
830.6320 Corrosion Character.	A	Non-corrosive in plastic	456232-01
830.6321 Dielectric breakdown	NA		

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

* Provide brief description, e.g., color--yellow or property value, e.g., density 1.25 g/cc; Unless otherwise indicated, the property should be at 25 ^{0}C.

[1] If product is dispersible with water

[2] If product is an emulsifiable liquid

Laird's Regulatory Consultants, Inc

Over 28 years Experience and Expertise in The Regulation of Pesticide Products

December 5, 2002

Mr. Adam Hayward PM 34
Environmental Protection Agency
Regulatory Management II
Antimicrobial Division (7510C)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Subject: AXEN 30
EPA FILE SYMBOL 72977-G
Replacement labels

Dear Mr. Hayward:

Per the attached letter from my client, I have enclosed five (5) copies of their desired labels for the product referenced above.

Please replace the labels which were submitted with the initial application with the attached labels.

Thank you for your assistance in this matter.

Sincerely,

Olivia D. Laird
President/Agent

Olivia D. Laird President/Owner * 501 South Lincoln Avenue, Sterling, VA 20164-2024* Phone 703/471-6500 * Fax 703/471-6269

INNOVATIVE MEDICAL SERVICES
a NASDAQ company

December 5, 2003

Ollvia Laird
Laird Regulatory Consultants
501 South Lincoln Ave.
Sterling, VA 20164-2024

Dear Olivia:

I have attached an updated label for our Axen 30 product currently under review with the EPA. After doing some research, we have added two graphics to the label to better communicate the use instructions to our customers.

If you have no changes upon review of this label, kindly submit it to the EPA for our current review.

Should you have any questions, please do not hesitate to contact me directly.

Best Regards,
INNOVATIVE MEDICAL SERVICES

Dolana Blount
Senior Microbiologist

1725 Gillespie Way • El Cajon, CA 92020 • Voice (619) 596-8600 • Facsimile (619) 596-8700

Laird's Regulatory Consultants, Inc

Over 28 years Experience and Expertise in The Regulation of Pesticide Products

October 3, 2002

457715-00

Mr. Adam Hayward PM 34
Environmental Protection Agency
Regulatory Management II
Antimicrobial Division (7510C)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Subject: AXEN 30
EPA FILE SYMBOL 72977-G
Data Referenced in Matrix

Dear Mr. Hayward:

Per our telephone conversation, This letter is to inform you and your team that the data, Toxicity, chemistry and basic efficacy data which are referenced in the Data Matrices in the initial application submission will support this application. This is just a lower concentration, ingredient statement, Silver than each of the substantially similar products, EPA REG. Nos 72977-1 and 72977-2. Please note, I have included Volumes 1 Administrative Materials, and 2 product specific chemistry data, with this submission to support this particular formulation.

<u>Please replace the labels which were submitted with the initial application with the attached labels.</u>

Thank you for your assistance with this application.

Sincerely,

Olivia D. Laird
President/Agent

Olivia D. Laird President/Owner * 501 South Lincoln Avenue, Sterling, VA 20164-2024* Phone 703/471-6590 * Fax 703/471-6269

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER & SPONSOR

SUBMITTER
LAIRD'S REGULATORY CONSULTANTS, INC.
501 SOUTH LINCOLN AVENUE
STERLING, VIRGINIA 20164-2024

SPONSOR
INNOVATIVE MEDICAL SERVICES
D/B/A ETI H_2O
1725 GILLESPIE WAY
EL CAJON, CA 92020

2. REGULATORY ACTION TO BE TAKEN

Submission of Additional Product Specific Chemistry Data

EPA FILE SYMBOL/REG. NO.: 72977-G

PRODUCT NAME: AXEN 30

TRANSMITTAL DATE

October 3, 2002

3. LIST OF SUMITTED STUDIES

Volume 1: Administrative Materials
45771501 **Volume 2: Chemistry Data**

COMPANY OFFICIAL: for **Dolana Blount**

COMPANY CONTACT: **OLIVIA D. LAIRD**
Phone: (703) 471-6590
FAX: (703) 471-6269

Mrs Olivia Laird
501 S Lincoln Ave
Sterling, VA 20164-2024

Mrs Olivia Laird
501 S Lincoln Ave
Sterling, VA 20164-2024

COVER PAGE

AXEX 30

EPA FILE SYMBOL - 72977-G

ADMINISTRATIVE MATERIALS

VOLUME I

TABLE OF CONTENTS

Laird's Regulatory Consultant

Laird's Regulatory Consultants, Inc

Over 28 years Experience and Expertise in The Regulation of Pesticide Products

457572-00

September 10, 2002

Mr. Marshall Swindell, PM 33
Environmental Protection Agency
Regulatory Management
Antimicrobial Division (7510C)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

72977-G

Subject: AXEN 30
EPA CO. NUMBER 72977-
Application for registration of a Me-too product

Dear Mr. Swindell:

Attached hereto please find an application for registration of a Me-too product which includes a total of 11 volumes with the Administrative volume. The supportive information is included on the matrices as well as MRID Numbers which are listed on the attached matrices.

Should you have questions/concerns please don't hesitate to contact me.

Sincerely,

Olivia D. Laird
President/Agent

Olivia D. Laird President/Owner * 501 South Lincoln Avenue, Sterling, VA 20164-2024* Phone 703/471-6590 * Fax 703/471-6269

TRANSMITTAL DOCUMENT

1. **NAME AND ADDRESS OF SUBMITTER & SPONSOR**

SUBMITTER
LAIRD'S REGULATORY CONSULTANTS, INC.
501 SOUTH LINCOLN AVENUE
STERLING, VIRGINIA 20164-2024

SPONSOR
INNOVATIVE MEDICAL SERVICES
1725 GILLESPIE WAY
EL CAJON, CA 92020

2. **REGULATORY ACTION TO BE TAKEN**

Submission of AOAC Use Dilution and Efficacy Data

3. **TRANSMITTAL DATE**
September 4, 2002

4. **LIST OF SUMITTED STUDIES**

45757201 **Volume 1.** Administrative
45757202 **Volume 2.** Chemistry
45757203 **Volume 3.** AOAC Use Dilution-Carrier Confirmation (lab sample ID-197155)
45757204 **Volume 4.** AOAC Use Dilution-Carrier Confirmation (lab sample ID-194972)
45757205 **Volume 5.** Fungicidal Activity of A Disinfectant
45757206 **Volume 6.** Evaluation of Axen for Residual Activity
45757207 **Volume 7.** Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces -Virus: Influenza a virus
45757208 **Volume 8.** Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Virus: Influenza a virus -Virus Human Immunodeficiency Virus Type 1
45757209 **Volume 9.** Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Virus: Herpes simplex virus type 1
45757210 **Volume 10.** Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Virus: Poliovirus type 2
Volume 11. Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Virus: Rhinovirus type 37

COMPANY OFFICIAL: for Dolana Blount Laird

COMPANY CONTACT: OLIVIA D. LAIRD
Phone: (703) 471-6590
FAX: (703) 471-6269

VIA FACSIMILE
(703) 308-6467

INNOVATIVE MEDICAL SERVICES
a NASDAQ company

January 14, 2003

Ian Blackwell
Efficacy Evaluation Team
Product Science Branch
Antimicrobial Division (7510C)
US EPA

Subject: Axen 30 Efficacy studies
EPA FILE SYMBOL 72977-G

Dear Mr. Blackwell

Thank you for your time this afternoon. This letter confirms that the below referenced studies were all testing efficacy of a 30ppm formulation of our disinfectant product, which is the equivalent of Axen 30.

MRID	Study Title
45757202	AOAC Use Dilution Carrier Confirmation (Lab Sample ID# 197155)
45757203	AOAC Use Dilution Carrier Confirmation (Lab Sample ID# 194972)
45757204	Fungicidal Activity of a Disinfectant
45757205	Evaluation of Axen for Residual Activity
45757206	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Virus:Influenza A virus
45757207	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Virus:Human Immunodeficiency Virus Type 1
45757208	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Virus:Herpes Simplex Virus type 1
45757209	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Poliovirus type 2
45757210	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Virus:Rhinovirus type 37

Please do not hesitate to contact me should you need additional information.

Sincerely,
INNOVATIVE MEDICAL SERVICES

Dolana Blount
Senior Microbiologist

1725 Gillespie Way • El Cajon, California 92020 • voice (619) 596-8900 • facsimile (619) 596-8700
www.imspure.com

FAX COVER

INNOVATIVE MEDICAL SERVICES
a NASDAQ company

DATE: 01/14/03

TO: Ian Blackwell
US EPA

FAX: 703-308-6467

FROM: Dolana Blount
INNOVATIVE MEDICAL SERVICES
PHONE: (619) 596-8600 Ext. 105
FAX: (619) 596-8700

MESSAGE:

As requested

Page 1 of 2

N|FT

B

COVER PAGE

Stabilized Ionic Silver
AXEN 30

Disinfectant, Fungicide & Virucide

EPA COMPANY NUMBER 72977-

ADMINISTRATIVE MATERIALS

VOLUME I

TABLE OF CONTENTS

INNOVATIVE MEDICAL SERVICES
a NASDAQ company

August 16, 2002

Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

To Whom It May Concern:

APPOINTMENT OF AUTHORIZED CONSULTANT REPRESENTATIVE

Innovative Medical Services hereby appoints Dr. Jerry Moore and Olivia Laird, Regulatory Consultants, to serve as Consultant Representatives of ETIH2O, a division of Innovative Medical Services and to act on its behalf with regard to all regulatory matters of Axen (72977-2) before the Office of Pesticide Programs of the U.S. Environmental Protection Agency.

Sincerely,
INNOVATIVE MEDICAL SERVICES

Dolana Blount
Assistant to the President/CEO

1725 Gillespie Way • El Cajon, CA 92020 • *telephone* (619) 596.8600 • facsimile (619) 596.8700
www.imspure.com

NIFT

6

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number: 269023

Application for Pesticide - Section I

1. Company/Product Number: 72977-G

2. EPA Product Manager: ~~Marshall Srinderl~~

3. Proposed Classification: ☒ None ☐ Restricted

4. Company/Product (Name): Axen 30

PM#: 34 ~~33~~

5. Name and Address of Applicant *(Include ZIP Code)*:
Innovative Medical Services
1725 Gillespie Way
El Cajon, California 92020

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.

☐ Resubmission in response to Agency letter dated _____

☐ Notification - Explain below.

☐ Final printed labels in response to Agency letter dated _____

☒ "Me Too" Application.

☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☒ Yes ☐ No	☐ Yes ☒ No	☐ Metal ☒ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
*tification must ubmitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: ☒ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions: ☒ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☒ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Olivia D. Laird	Consultant/Agent	(703) 471-6590

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: [signature]

3. Title: Senior MicroBiologist

4. Typed Name: for Dolana Blount

5. Date: September 11, 2002

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EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registrat[redacted] action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrat[redacted] that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible f[redacted] expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identic[redacted] your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too" reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.
Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
ETI H_2O, 1725 Gillespie Way, El Cajon, CA 92020	72977-S
Active Ingredient(s) and/or representative test compound(s): Silver and Citric Acid	Date: September 10, 2002
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158): Disinfectat, Fungicide & Viruçide	Product Name: AXEN 30

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Olivia D. Laird for Delana	9/10/02	Olivia D. Laird/Agent

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Laird's Regulatory Consultants, Inc

Over 28 years Experience and Expertise in The Regulation of Pesticide Products

September 10, 2002

Mr. Marshall Swindell, PM 33
Environmental Protection Agency
Regulatory Management
Antimicrobial Division (7510C)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Subject: AXEN 30
EPA CO. NUMBER 72977-
Application for registration of a Me-too product

Dear Mr. Swindell:

Attached hereto please find an application for registration of a Me-too product which includes a total of 11 volumes with the Administrative volume. The supportive information is included on the matrices as well as MRID Numbers which are listed on the attached matrices.

Should you have questions/concerns please don't hesitate to contact me.

Sincerely,

Olivia D. Laird
President/Agent

Olivia D. Laird President/Owner * 501 South Lincoln Avenue, Sterling, VA 20164-2024* Phone 703/471-6590 * Fax 703/471-6269

TRANSMITTAL DOCUMENT

1. **NAME AND ADDRESS OF SUBMITTER & SPONSOR**

SUBMITTER
LAIRD'S REGULATORY CONSULTANTS, INC.
501 SOUTH LINCOLN AVENUE
STERLING, VIRGINIA 20164-2024

SPONSOR
INNOVATIVE MEDICAL SERVICES
1725 GILLESPIE WAY
EL CAJON, CA 92020

2. **REGULATORY ACTION TO BE TAKEN**

Submission of AOAC Use Dilution and Efficacy Data

3. **TRANSMITTAL DATE**
September 4, 2002

4. **LIST OF SUMITTED STUDIES**

Volume 1. Adminstrative
Volume 2. Chemistry
Volume 3. AOAC Use Dilution-Carrier Confirmation
Volume 4. AOAC Use Dilution-Carrier Confirmation
Volume 5. Fungicidal Activity of A Disinfactant
Volume 6. Evaluation of Axen for Residual Activity
Volume 7. Virucidal Efficacy of a Disinfactant for Use on Inanimate Environmental Surfaces -Virus: Influenza a virus
Volume 8. Virucidal Efficacy of a Disinfactant for Use on Inanimate Environmental Surfaces Virus: Influenza a virus -Virus Human Immunodeficiency Virus Type 1
Volume 9. Viracidal Efficacy of a Disinfactant for Use on Inanimate Environmental Surfaces Virus: Herpes simplex virus type 1
Volume 10. Virucidal Efficacy of a Disinfactant for Use on Inanimate Environmental Surfaces Virus: Pollovirus type 2
Volume 11. Virucidal Efficacy of a Disinfactant for Use on Inanimate Environmental Surfaces Virus: Rhinovirus type 37

COMPANY OFFICIAL: for Dolana Blount

COMPANY CONTACT: OLIVIA D. LAIRD
Phone: (703) 471-6590
FAX: (703) 471-6269

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DATA MATRIX

Date	August 21, 2002	EPA Reg No./File Symbol	72977-	Page 2 of 4
Applicant's/Registrant's Name & Address	Innovative Medical Services 1725 Gillespie Way, El Cajon, California 92020	Product	AXEN 30	
Ingredient	Silver and Citric Acid			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6313	Stability	451610-01	ETI H_2O		
830.6314	Oxidiation/Reduction	451610-01	ETI H_2O		
830.6315	Flammability	451610-01	ETI H_2O		
830.6316	Explodability	451610-01	ETI H_2O		
830.6317	Storage Stability	456232-01	ETI H_2O		
830.7100	Viscosity	451610-01	ETI H_2O		
830.6319	Miscibility	451610-01	ETI H_2O		
830.6320	Corrosion Characteristic	451610-01	ETI H_2O		
830.6321	Dielectric Breakdown Voltage	451610-01	ETI H_2O		
830.7000	pH	451610-01	ETI H_2O		
830.7050	UV/Visible absorption	451610-01	ETI H_2O		
830.7100	Viscosity	451610-01	ETI H_2O		
830.7200	Melting Point	451610-01	ETI H_2O		
830.7220	Boiling Point	451610-01	ETI H_2O		
830.7300	Density/Bulk Density	451610-01	ETI H_2O		

Signature	Name and Title	Date
Olivia D. Laird	Olivia D. Laird/Consultant/Agent	8/21/02

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DATA MATRIX

Date	August 21, 2002	EPA Reg No./File Symbol	72077-	Page 1 of 1
Applicant's/Registrant's Name & Address	Innovative Medical Services 1725 Gillespie Way, El Cajon, California 92020	Product	AXEN 30	
Ingredient	Silver and Citric Acid			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6313	Stability	451610-01	ETI H_2O		
830.6314	Oxidation/Reduction	451610-01	ETI H_2O		
830.6315	Flammability	451610-01	ETI H_2O		
830.6316	Explodability	451610-01	ETI H_2O		
830.6317	Storage Stability	456232-01	ETI H_2O		
830.7100	Viscosity	451610-01	ETI H_2O		
830.6319	Miscibility	451610-01	ETI H_2O		
830.6320	Corrosion Characteristic	451610-01	ETI H_2O		
830.6321	Dielectric Breakdown Voltage	451610-01	ETI H_2O		
830.7000	pH	451610-01	ETI H_2O		
830.7050	UV/Visible Absorption	451610-01	ETI H_2O		
830.7100	Viscosity	451610-01	ETI H_2O		
830.7200	Melting Point	451610-01	ETI H_2O		
830.7220	Boiling Point	451610-01	ETI H_2O		
830.7300	Density/Bulk Density	451610-01	ETI H_2O		

Signature	Name and Title	Date
David A. Kent	Olivia D. Lair/Consultant/Agent	9/21/02

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DATA MATRIX

Date: August 21, 2002	EPA Reg No./File Symbol: 72977-	Page 2 of 4
Applicant's/Registrant's Name & Address: Innovative Medical Services, 1725 Gillespie Way, El Cajon, California 92020	Product: AXEN 30	
Ingredient: Silver and Citric Acid		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6313	Stability	451610-01	RTI H_2O		
830.6314	Oxidation/Reduction	451610-01	RTI H_2O		
830.6315	Flammability	451610-01	RTI H_2O		
830.6316	Explodability	451610-01	RTI H_2O		
830.6317	Storage Stability	456232-01	RTI H_2O		
830.7100	Viscosity	451610-01	RTI H_2O		
830.6319	Miscibility	451610-01	RTI H_2O		
830.6320	Corrosion Characteristic	451610-01	RTI H_2O		
830.6321	Dielectric Breakdown Voltage	451610-01	RTI H_2O		
830.7000	pH	451610-01	RTI H_2O		
830.7050	UV/Visible absorption	451610-01	RTI H_2O		
830.7100	Viscosity	451610-01	RTI H_2O		
830.7200	Melting Point	451610-01	RTI H_2O		
830.7220	Boiling Point	451610-01	RTI H_2O		
830.7300	Density/Bulk Density	451610-01	RTI H_2O		

Signature: Olivia D. Laird for L. Hunt	Name and Title: Olivia D. Laird/Consultant/Agent	Date: 8/21/02

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INSTRUCTIONS FOR DATA MATRIX

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If the cite-all method is used for all data supporting this particular ingredient, enter "CITE-ALL" in the Guideline Reference Number column and leave the Guideline Study Name column blank. If the cite-all method is used for a particular Guideline Reference Number enter "CITE-ALL" in the MRID Number column on the line for that Guideline Reference Number. In either case, enter all submitters to whom offers to pay have been sent on subsequent lines. [Note: if the selective method of support is used and written authorization (letter of permission) is provided, the individual Guideline Reference Number, Guideline Study Name, and MRID Number columns must still be completed.] Otherwise:

Guideline Reference Number: Enter on separate lines in numerical order the Guideline Reference Numbers from 40 CFR Part 158 for all studies cited to support the registration/reregistration for this ingredient.

Guideline Study Name: For each Guideline Reference Number cited, enter the corresponding Guideline Study Name.

MRID Number: For each individual study cited in support of a Guideline Reference Number and Guideline Study Name, enter the Master Record Identification (MRID) Number listed in the Pesticide Document Management System (PDMS). Enter only one MRID Number on each line. Note that more than one MRID Number may be required per Guideline Reference Number. Note: Occasionally a study required to maintain a registration/reregistration is not associated with a Guideline Reference Number and Guideline Study Name. In such case, enter the MRID Number(s) for the study(ies).

Submitter: Using the most recent Data Submitters List, identify the Original Data Submitter with their current address for each study cited. The EPA assigned company number or other abbreviation may be used. Clearly explain any variations (alternate addresses, data owners not on the Data Submitters List, etc.) in footnotes to this table.

Status: Enter one of the following codes for each study cited, as appropriate:

OWN:	I am the Original Data Submitter for this study.
EXC:	I have obtained written permission of the Original Data Submitter to cite this exclusive-use study in support of this application.
PER:	I have obtained the permission of the Original Data Submitter to use this study in support of this application.
OLD:	The study was submitted more than 15 years ago and all periods of compensation have expired.
PL:	The study is in the public literature.
PAY:	I have notified in writing the Original Data Submitter or, if the cite-all method is used, all companies listed in the most current Data Submitters List for this ingredient, and have offered (a) to pay compensation in accordance with FIFRA sections 3(c)(1)(F) and/or 3(c)(2)(B), and (b) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study(ies).
GAP:	This Guideline data requirement is a data gap as defined in 40 CFR sections 152.83(a) and 152.96.
FOR:	I am taking the formulator's exemption for this ingredient only. Other columns of this line should be marked "NA". However, if this product is to be registered/reregistered for additional uses for which the purchased EPA registered ingredient is not supported, additional data must be submitted or cited here to support those uses.
Note:	If additional explanation is needed, enter a footnote number in this column and attach the corresponding explanation.

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DATA MATRIX

Date	August 21, 2002	EPA Reg No./File Symbol	72977-	Page 3 of 4
Applicant's/Registrant's Name & Address	Innovative Medical Services 1725 Gillespie Way, El Cajon,California 92020	Product	AXEN 30	
Ingredient	Silver and Citric Acid			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7370	Dissociation Constant	451610-01	ETI H_2O		
830.7520	Particle Size	451610-01	ETI H_2O		
830.7550	Partition Coefficient (n-				
	octanol/water), shake flask method	451610-01	ETI H_2O		
830.7560	Partition Coefficient (n-				
	octanol/H_2O) generator column method	451610-01	ETI H_2O		
830.7570	Partition Coefficient (n-				
	octanol/water,est. by liquid chromatography				
		451610-01	ETI H_2O		
830.7840	Solubility (column elution	451610-01	ETI H_2O		
830.7860	Solubility (generator column)				
		451610-01	ETI H_2O		
830.7950	Vapor Pressure	451610-01	ETI H_2O		
870.1100	Acute Oral & Percutaneous				
	Toxicity in Rats	450169-01	ETI H_2O		

Signature	Name and Title	Date
for D Blount	Olivia D. Laird/Consultant/Agent	8/21/02

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DATA MATRIX

Date	August 21, 2002	EPA Reg No./File Symbol	72977-	Page 1 of 4
Applicant's/Registrant's Name & Address	Innovative Medical Services 1725 Gillespie Way, El Cajon, California 92020	Product	AXEN 30	

Ingredient: Silver and Citric Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7370	Dissociation Constant	451610-01	ETI H_2O		
830.7[illegible]	Particle Size	451610-01	ETI H_2O		
830.7560	Partition Coefficient (n-octanol/water), shake flask method	451610-01	ETI H_2O		
830.7560	Partition Coefficient (n-octanol/water), generator column method	451610-01	ETI H_2O		
830.7570	Partition Coefficient (n-octanol/water, est. by liquid chromatography				
		451610-01	ETI H_2O		
830.7840	Solubility (column elution)	451610-01	ETI H_2O		
830.7860	Solubility (generator column)				
		451610-01	ETI H_2O		
830.7950	Vapor Pressure	451610-01	ETI H_2O		
870.1100	Acute Oral & Percutaneous Toxicity in Rats	451140-01	ETI H_2O		

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Signature	Name and Title	Date
Olivia D. Blair	Olivia D. Blair/Consultant/Agent	8/21/02

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DATA MATRIX

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Applicant's/Registrant's Name & Address	Innovative Medical Services 1725 Gillespie Way, El Cajon, California 92020	Product	AXEN 30	

Ingredient: Silver and Citric Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7370	Dissociation Constant	451610-01	ETI H_2O		
830.7520	Particle Size	451610-01	ETI H_2O		
830.7550	Partition Coefficient (n-				
	octanol/water), shake flask method	451610-01	ETI H_2O		
830.7560	Partition Coefficient (n-				
	octanol/H_2O) generator column method	451610-01	ETI H_2O		
830.7570	Partition Coefficient (n-				
	octanol/water, est. by liquid chromatography				
		451610-01	ETI H_2O		
830.7840	Solubility (column elution)	451610-01	ETI H_2O		
830.7860	Solubility (generator column)				
		451610-01	ETI H_2O		
830.7950	Vapor Pressure	451610-01	ETI H_2O		
870.1100	Acute Oral & Percutaneous				
	Toxicity in Rats	450169-01	ETI H_2O		

Signature	Name and Title	Date
for Laird	Olivia D. Laird/Consultant/Agent	8/21/02

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DATA MATRIX

Date: August 21, 2002	EPA Reg No./File Symbol: 72977-	Page 1 of 4
Applicant's/Registrant's Name & Address: Innovative Medical Services, 1725 Gillespie Way, El Cajon, California 92020	Product: AXEN 30	
Ingredient: Silver and Citric Acid		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
5 830.1550	Product Identity, Composition	451610-01	ETI H_2O		
830.1600	Discription of materials used				
	to produce the product	451610-01	ETI H_2O		
830.1620	Manufacturing Preocess	451610-01	ETI H_2O		
830.1650	Discription of formulation				
	Process	451610-01	ETI H_2O		
830.1670	Discussion of formation of				
	Impurities	451610-01	ETI H_2O		
830.1700	Preliminary Analysis	451610-01	ETI H_2O		
830.1750	Certified Limits	451610-01	ETI H_2O		
830.1800	Enforcement Analytical Met.	451610-01	ETI H_2O		
830.1900	Submittal of Samples	451610-01	ETI H_2O		
830.6302	Color	451610-01	ETI H_2O		
830.6303	Physical State	451610-01	ETI H_2O		
830.6304	Odor	451610-01	ETI H_2O		

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Signature: Olivia Laird for D. Blount

Name and Title: Olivia D. Laird/Consultant/Agent

Date: 8/21/02

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401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date	August 21, 2002	EPA Reg No./File Symbol	72077-	Page 1 of 4
Applicant's/Registrant's Name & Address	Innovative Medical Services 4725 Gillespie Way, El Cajon, California 92020	Product	AXEN 30	
Ingredient	Silver and Citric Acid			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity, Composition	451610-01	ETI H_2O		
830.1600	Distribution of materials used				
	to produce the product	451610-01	ETI H_2O		
830.1620	Manufacturing Process	451610-01	ETI H_2O		
830.1650	Discription of formulation				
	Process	451610-01	ETI H_2O		
830.1670	Discussion of formation of				
	Impurities	451610-01	ETI H_2O		
830.1700	Preliminary Analysis	451610-01	ETI H_2O		
830.1750	Certified Limits	451610-01	ETI H_2O		
830.1800	Enforcement Analytical Met.	451610-01	ETI H_2O		
830.1900	Submittal of Samples	451610-01	ETI H_2O		
830.6302	Color	451610-01	ETI H_2O		
830.6303	Physical State	451610-01	ETI H_2O		
830.6304	Odor	451610-01	ETI H_2O		

Signature	Name and Title	Date
	Olivia D. Laird/Consultant/Agent	8/21/02

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DATA MATRIX

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Applicant's/Registrant's Name & Address	Innovative Medical Services 1725 Gillespie Way, El Cajon, California 92020	Product	AXEN 30	

Ingredient: Silver and Citric Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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	to produce the product	451610-01	ETI H_2O		
830.1620	Manufacturing Preocess	451610-01	ETI H_2O		
830.1650	Discription of formulation				
	Process	451610-01	ETI H_2O		
830.1670	Discussion of formation of				
	Impurities	451610-01	ETI H_2O		
830.1700	Preliminary Analysis	451610-01	ETI H_2O		
830.1750	Certified Limits	451610-01	ETI H_2O		
830.1800	Enforcement Analytical Met.	451610-01	ETI H_2O		
830.1900	Submittal of Samples	451610-01	ETI H_2O		
830.6302	Color	451610-01	ETI H_2O		
830.6303	Physical State	451610-01	ETI H_2O		
830.6304	Odor	451610-01	ETI H_2O		

Signature	Name and Title	Date
	Olivia D. Laird/Consultant/Agent	8/21/02

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MRID Number: For each individual study cited in support of a Guideline Reference Number and Guideline Study Name, enter the Master Record Identification (MRID) Number listed in the Pesticide Document Management System (PDMS). Enter only one MRID Number on each line. Note that more than one MRID Number may be required per Guideline Reference Number. Note: Occasionally a study required to maintain a registration/reregistration is not associated with a Guideline Reference Number and Guideline Study Name. In such case, enter the MRID Number(s) for the study(ies).

Submitter: Using the most recent Data Submitters List, identify the Original Data Submitter with their current address for each study cited. The EPA assigned company number or other abbreviation may be used. Clearly explain any variations (alternate addresses, data owners not on the Data Submitters List, etc.) in footnotes to this table.

Status: Enter one of the following codes for each study cited, as appropriate:

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EXC:	I have obtained written permission of the Original Data Submitter to cite this exclusive-use study in support of this application.
PER:	I have obtained the permission of the Original Data Submitter to use this study in support of this application.
OLD:	The study was submitted more than 15 years ago and all periods of compensation have expired.
PL:	The study is in the public literature.
PAY:	I have notified in writing the Original Data Submitter or, if the cite-all method is used, all companies listed in the most current Data Submitters List for this ingredient, and have offered (a) to pay compensation in accordance with FIFRA sections 3(c)(1)(F) and/or 3(c)(2)(B), and (b) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study(ies).
GAP:	This Guideline data requirement is a data gap as defined in 40 CFR sections 152.83(a) and 152.99.
FOR:	I am taking the formulator's exemption for this ingredient only. Other columns of this line should be marked "NA". However, if this product is to be registered/reregistered for additional uses for which the purchased EPA registered ingredient is not supported, additional data must be submitted or cited here to support those uses.
Note:	If additional explanation is needed, enter a footnote number in this column and attach the corresponding explanation.

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WASHINGTON, D.C. 20460

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DATA MATRIX

Date	August 21, 2002	EPA Reg No./File Symbol	72977-	Page 4 of 4
Applicant's/Registrant's Name & Address	Innovative Medical Services 1725 Gillespie Way, El Cajon,California 92020	Product	AXEN 30	
Ingredient	Silver and Citric Acid			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1200	**Acute Dermal Irritation Rab**	**450169-04**	**ETI H_2O**		
870.1300	Acute Inhalation Toxicity	451610-01	ETI H_2O		
870.2400	Primary Eye Irritation Rab.	451610-01	ETI H_2O		
870.2500	Primary Dermal Irritation	450169-02	ETI H_2O		
870.2600	Dermal Sensitization G. Pigs	450169-05	ETI H_2O		
92.2	AOAC Use Dilution Confirmation	Attached	ETI H_2O	Own	
92.2	AOAC Use Dilution Confirmation	Attached	ETI H_2O		
92.2	Fungicidal Activity	Attached	ETI H_2O		
92.2	Residual Activity	Attached	ETI H_2O		
92.2	Virucidal Efficacy	Attached	ETI H_2O		
92.2	Virucidal Efficacy	Attached	ETI H_2O		
92.2	Virucidal Efficacy	Attached	ETI H_2O		
92.2	Virucidal Efficacy	Attached	ETI H_2O		
92.2	Virucidal Efficacy	Attached	ETI H_2O		

Signature	Name and Title	Date
Olivia D. Laird for D. Blount	Olivia D. Laird/Consultant/Agent	8/21/02

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DATA MATRIX

Date	August 21, 2002	EPA Reg No./File Symbol	72077-	Page 1 of 1
Applicant's/Registrant's Name & Address	Innovative Medical Services 1725 Gillespie Way, El Cajon, California 92020	Product	AXEN 30	

Ingredient: Silver and Citric Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1200	Acute Dermal Irritation Rab	450169-04	ETI H_2O		
870.1300	Acute Inhalation Toxicity	451610-01	ETI H_2O		
870.2400	Primary Eye Irritation Rab.	451610-01	ETI H_2O		
870.2500	Primary Dermal Irritation	450169-02	ETI H_2O		
870.2600	Dermal Sensitization G. Pigs	450169-05	ETI H_2O		
92.2	AOAC Use Dilution Confirmation	Attached	ETI H_2O	Dup	
92.2	AOAC Use Dilution Confirmation	Attached	ETI H_2O		
92.2	Fungicidal Activity	Attached	ETI H_2O		
92.2	Residual Activity	Attached	ETI H_2O		
92.2	Virucidal Efficacy	Attached	ETI H_2O		
92.2	Virucidal Efficacy	Attached	ETI H_2O		
92.2	Virucidal Efficacy	Attached	ETI H_2O		
92.2	Virucidal Efficacy	Attached	ETI H_2O		
92.2	Virucidal Efficacy	Attached	ETI H_2O		

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Signature	Name and Title	Date
Olivia D. Laird	Olivia D. Laird/Consultant/Agent	8/21/02

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WASHINGTON, D.C. 20460

DATA MATRIX

Date	August 21, 2002	EPA Reg No./File Symbol	72977-	Page 4 of 4
Applicant's/Registrant's Name & Address	Innovative Medical Services 1725 Gillespie Way, El Cajon, California 92020	Product	AXEN 30	

Ingredient: Silver and Citric Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1200	Acute Dermal Irritation Rab	450169-04	ETI H_2O		
870.1300	Acute Inhalation Toxicity	451610-01	ETI H_2O		
870.2400	Primary Eye Irritation Rab.	451610-01	ETI H_2O		
870.2500	Primary Dermal Irritation	450169-02	ETI H_2O		
870.2600	Dermal Sensitization G. Pigs	450169-05	ETI H_2O		
92.2	AOAC Use Dilution Confirmation	Attached	ETI H_2O	Own	
92.2	AOAC Use Dilution Confirmation	Attached	ETI H_2O		
92.2	Fungicidal Activity	Attached	ETI H_2O		
92.2	Residual Activity	Attached	ETI H_2O		
92.2	Virucidal Efficacy	Attached	ETI H_2O		
92.2	Virucidal Efficacy	Attached	ETI H_2O		
92.2	Virucidal Efficacy	Attached	ETI H_2O		
92.2	Virucidal Efficacy	Attached	ETI H_2O		
92.2	Virucidal Efficacy	Attached	ETI H_2O		

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Signature: Olivia D. Laird for O. Hunt

Name and Title: Olivia D. Laird/Consultant/Agent

Date: 8/21/02

INSTRUCTIONS FOR DATA MATRIX

INSTRUCTIONS: Identify all data submitted or cited and all submitters from whom permission has been received or to whom offers to pay have been sent by entering sufficient information in the attached matrix (photocopy and attach additional pages as necessary). Complete all columns; omission of essential information will delay approval of the registration/reregistration. On each page enter the date, Applicant's/Registrant's name, EPA Registration Number or application file symbol of the product, ingredient, page number, and total number of pages.

The Data Compensation Form entitled "Certification with Respect to Citation of Data" and the Data Matrix will be publicly available, except for the Guideline Reference Number, Guideline Study Name, and MRID Number columns after the registration/reregistration of this product has been granted or once this form is received in response to a Data-Call-In Notice. However, the information in the Guideline Reference Number, Guideline Study Name, and MRID Number columns is available through the Freedom of Information Act in association with the EPA Registration Number.

Ingredient: Identify the active ingredient(s) in this product for which data are cited. The active ingredient(s) are to be identified by entering the chemical name and the CAS registry number. Begin a new page for each separate active ingredient for which data are cited. If bridging data from a related chemical or representative test compound are cited, enter the identity of that chemical/representative test compound including the EPA Registration Number/File Symbol if appropriate.

If the cite-all method is used for all data supporting this particular ingredient, enter "CITE-ALL" in the Guideline Reference Number column and leave the Guideline Study Name column blank. If the cite-all method is used for a particular Guideline Reference Number enter "CITE-ALL" in the MRID Number column on the line for that Guideline Reference Number. In either case, enter all submitters to whom offers to pay have been sent on subsequent lines. [Note: If the selective method of support is used and written authorization (letter of permission) is provided, the individual Guideline Reference Number, Guideline Study Name, and MRID Number columns must still be completed.] Otherwise:

Guideline Reference Number: Enter on separate lines in numerical order the Guideline Reference Numbers from 40 CFR Part 158 for all studies cited to support the registration/reregistration for this ingredient.

Guideline Study Name: For each Guideline Reference Number cited, enter the corresponding Guideline Study Name.

MRID Number: For each individual study cited in support of a Guideline Reference Number and Guideline Study Name, enter the Master Record Identification (MRID) Number listed in the Pesticide Document Management System (PDMS). Enter only one MRID Number on each line. Note that more than one MRID Number may be required per Guideline Reference Number. Note: Occasionally a study required to maintain a registration/reregistration is not associated with a Guideline Reference Number and Guideline Study Name. In such case, enter the MRID Number(s) for the study(ies).

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Note:	If additional explanation is needed, enter a footnote number in this column and attach the corresponding explanation.

Page _____ is not included in this copy.

Pages 183 through 185 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

__X___ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.

_____ Attorney-Client Privilege.

_____ Claimed Confidential by submitter upon submission to the Agency.

_____ Internal Deliberative Information.

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* The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
